IN THE UNITED STATES DISTRICT COURT
FOR THE EASTERN DISTRICT OF TEXAS
MARSHALL DIVISION

RETRACTABLE TECHNOLOGIES INC.	*	Civil Docket No.
	*	2:07-CV-250
VS.	*	Marshall, Texas
	*	
	*	November 3, 2009
BECTON DICKINSON & COMPANY	*	9:00 A.M.

TRANSCRIPT OF JURY TRIAL
BEFORE THE HONORABLE DAVID FOLSOM
UNITED STATES DISTRICT JUDGE

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P R O C E E D I N G S

(Jury in.)

THE COURT: Please be seated.

Good morning, Ladies and Gentlemen. I hope everyone had a pleasant evening.

You may continue your cross-examination.

MS. PIROZZOLO: Thank you, Your Honor.

NEIL SHEEHAN, PLAINTIFF'S WITNESS, SWORN

CROSS-EXAMINATION CONTINUED

BY MS. PIROZZOLO:

Q. Good morning, Mr. Sheehan.
A. Good morning, ma'am.
Q. I'd like to go back to talking about the Integra 1mL syringe, if we can.
A. Sure.
Q. I want to put up Defendant's Exhibit 311, Page 27.
That is the Integra 1mL syringe, correct?
A. Yes, ma'am.
Q. Now, I want to put up Defendant's Exhibit 311, Page 34.
That shows the -- what BD refers to as the hub of the 1mL Integra syringe, correct?
A. That's what it looks like, yes, ma'am.
Q. And the needle is glued into the hub, correct?
A. Yes, it is.
Q. Now, I want to put up Defendant's Exhibit 311, Page 8.
This exhibit shows how the hub fits into the syringe body, correct?
A. Well, it shows how the hub fits into a cross-section of the syringe body. Once you cut open a -- a cylindrical body, it's going to splay open a little bit, so you shouldn't do any evaluation or measuring or examination with it.

But I will concur that generally speaking, it looks like it's in about the right place in the nose.

Q. Okay. Now, the Integra 1mL syringe has a cutter, correct?

A. Yes.

Q. Okay. I want to put up Defendant's Exhibit 311, Page 18.

This metal piece is the cutter in the Integra 1mL syringe, correct?

A. Yes, ma'am.

Q. The cutter is located in front of the needle hub, correct?

A. Yes. Yes.

Q. Now, yesterday you said that the 1ml syringe would still work if you took the cutter out of the syringe, correct?

A. Well, what I said is that I was able to operate -- I was able to -- when I took apart a 1ml syringe and I took the cutter out, just out of curiosity, just to see if it would work and I could -- I could get it to work without the cutter.

Q. I want to show you a clip of your deposition.

MS. PIROZZOLO: Dennis, could you play that?

(Video playing.)

QUESTION: And if you were to remove the cutter from the 1-mil Integra syringe, you would not be able to retract the needle, right?

ANSWER: That is correct.

(End of video clip.)

Q. (By Ms. Pirozzolo) Is that what you said in your deposition, sir?

A. That's what I said in my deposition, but that's before I did the testing that was the subject of a later deposition. And that's the time when I activated it without the cutter.

Q. Okay. And you didn't disclose that in your expert -- initial expert report, correct?

A. No. It's not in the initial report, no.

Q. Now, RTI is accusing BD's 1mL Integra of infringing Claims 43, 55, and 60 of the '224 patent, correct?

A. Yes, ma'am.

Q. And all those claims require a continuous retainer member, correct?

A. Yes. That -- that claim has that language. Those -- those claims have that language, yes.

Q. I want to put up the Court's construction of continuous retainer member.

So that has been defined as a non-retractable part of the retraction mechanism that encircles the inner head of the needle-holder and uses some clamping or frictional force to keep the needle in the projecting position until that clamping or frictional force is released, correct?

A. Yes, ma'am.

Q. Now, I want to focus on the first part of the definition, the frictional force used to keep the needle in the projecting position, okay?

A. Okay. It's not the first part, but sure.

Q. I want to focus on that part --

A. Okay.

Q. -- of the claim construction, okay?

A. Sure.

Q. Now, the body of the Integra 1mL syringe has two raised rings inside of it, correct?

A. That is correct.

Q. And I want to put up Defendant's Exhibit 311, Page 6.

These are the two rings here, correct?

A. That is correct.

Q. Okay. And the ring closer to the back of -- back end of the barrel is called a hub retainer ring, correct?

A. I think it's called a hub retaining ring.

Q. Hub retaining ring?
A. I think so. It's on the drawing.
Q. Okay. And the ring closer to the front is called the hub location ring, correct?
A. Yes. That's my recollection.
MS. PIROZZOLO: Now, Exhibit 311, 34, can we put that up?
Q. (By Ms. Pirozzolo) Now, this shows the needle-holder we just saw?
A. That's correct on the 1mL Integra.
Q. And that needle-holder has a groove along the outer periphery, correct?
A. Correct. It has a single groove that goes all the way around the outside.
Q. Okay. And that groove fits into the location ring in the barrel of the 1ml syringe, correct?
A. Yes, ma'am, as they showed.
Q. Now, you testified that prior to assembly, the needle hub of the Integra 1mL syringe is larger than the seal area of the barrel, correct?
A. It's larger than what's called the -- what -- BD refers to a certain part in the barrel drawing as the seal area, but that part is larger than not only the seal area; it's larger than the location ring area and the area just in front of it further into the nose.

Q. Now, you have testified that the best measure in your view of the frictional forces in the Integra 1mL syringe is the dimensions of the needle hub in the barrel, correct?

A. It's the most -- it's the most direct and the most straightforward. And those of us who know about press fits and things would understand and would appreciate that that's the -- that is what generates the frictional force.

Q. Okay.

A. That keeps the needle in the projecting position.

Q. Okay. You've also said there's no way to actually measure the frictional forces, correct?

A. What I said -- I used the analogy, if you put two people on a scale, Bob and Mary, you can't tell how much Bob weighs and how much Mary weighs.

So if you were to do a test pushing back on the needle, you're going to get a measure of both the frictional force and a measure of this mechanical force that occurs at the -- at the retaining ring area.

So that's why I conducted the test that I was attempting to describe yesterday, to try to tease out just about how much the frictional force was.

Q. So just -- if I can focus you on this question. You agree that there's no way to measure the actual frictional force between the barrel and the hub, correct?

A. None that I can think of, no.

Q. So your testing is an approximation of that force, correct?

A. My test -- my testing is more than just an approximation. I got an actual number based on actual testing, and it took other factors into account.

So I will give you this: That it is a range, so, therefore, I guess, sure, an approximation. That's fine.

Q. Now, in addition to frictional forces, I think you've just said there are mechanical forces, correct?

A. Yes. There is a mechanical force owing to the fact that there is a mechanical interface, if you will, between the location ring -- hub location ring and the groove that goes into it. One must be fair and take that into account.

Q. So there's a mechanical force between that groove in the needle hub and the bump on the inside of the barrel, correct?

A. Yes, ma'am.

Q. But you did not measure the mechanical contribution versus the frictional contribution in the

Integra 1mL syringe, correct?
A. That's correct, for the simple reason that you likewise cannot do that separately.
Q. You did not measure it, correct?
A. Okay. I did not measure it.
Q. Now, I want to talk about retraction in the Integra 1mL syringe.
To retract the needle, the cutter cuts through the hub, correct?
A. I'm sorry. Could you repeat?
Q. During retraction of the needle in the Integra 1mL syringe, the cutter cuts through the hub, correct?
A. It cuts through what BD terms the hub, yes, through the bridging portion.
Q. The outer portion of the hub remains in the front of the syringe after retraction, correct?
A. Correct. It -- it's non-retractable.
Q. And you call that outer portion the retainer member, correct?
A. Correct.
Q. So the retainer member remains held by friction after retraction, correct?
A. That's fine. Yeah, sure.
Q. Now, I'd like to talk about the BD Integra syringes and the Saf-T-Med syringe, okay?

A. Okay.
Q. And I'm going to put up a slide, D60. Now, this shows the Saf-T-Med syringe, correct?
A. I've only seen that prototype once at a deposition.
MR. HARDIN: Your Honor, can we have a limiting instruction, No. 1, please?
THE COURT: Very well.
Ladies and Gentlemen of the Jury, if you recall in the preliminary instructions, I told you from time to time I would give you limiting instructions, and this is one such example.
The Court instructed you in its preliminary jury instructions that the Court may from time to time instruct you on when some item of evidence is received for a limited purpose only. This is one such example.
You will hear evidence about prior art patents, such as the McGary patent, and about a prior art device owned by a company called Saf-T-Med. You should not consider this evidence in determining alleged infringement.
The Court admits such evidence for the limited purpose of showing alleged invalidity and rebutting Plaintiff's allegations that any alleged

infringement was willful.

And I'll give you a copy of this at some point in time to put in your jury notebook.

Thank you.

Q. (By Ms. Pirozzolo) Now, Mr. Sheehan, you have offered an opinion that you believe BD copied the patented invention, correct?

A. That's correct.

Q. Now, this slide, do you agree, based on your review of the Saf-T-Med syringe at your deposition, that this is a picture of the Saf-T-Med syringe?

A. It sure looks like it.

Q. And the middle figure is a figure from the McGary '010 patent, correct?

A. Yes, ma'am, it is.

Q. And the third picture on this demonstrative is a picture of the plunger of the Integra 3mL syringe, which has been penetrated by the cutter, correct?

A. That's correct.

Q. Now, the Saf-T-Med syringe has a cutter in it, correct?

A. Yes, ma'am.

Q. The cutter is located behind the plunger seal, correct?

A. Yes.

Q. And the cutter is required to activate the Saf-T-Med device, correct?
A. Yes.
Q. Now, the McGary patent discloses a cutter here in yellow, correct?
A. Yes, in the highlighted area. Yes.
Q. And in the McGary patent, the cutter is located behind the plunger, correct?
A. Yes, ma'am.
Q. In the McGary patent, the cutter is required for retraction, correct?
A. According to the patent, yes.
Q. Now, in the BD Integra 3mL syringe, that has a cutter in it, correct?
A. Yes, ma'am.
Q. The cutter is located behind the plunger seal, correct?
A. Well, it was until this. Yes.
Q. Before retraction, the cutter is located behind the plunger seal, correct?
A. Yes, ma'am.
Q. And in the Integra 3mL syringe, the cutter is required for retraction, correct?
A. Yes, ma'am.
Q. The BD 1mL Integra syringe also has a cutter

in it, correct?
A. Yes, ma'am.
Q. Now, I want to put up another slide.
MS. PIROZZOLO: D61, please.
Q. (By Ms. Pirozzolo) Now, this is a picture of the Saf-T-Med syringe, correct?
A. Yes, it looks like it.
Q. The middle figure is Figure 10 from the McGary patent, correct?
A. I recognize it.
Q. And the third figure is the Integra 3mL syringe, correct?
A. Yes, ma'am.
Q. Now, the Saf-T-Med syringe has a detachable needle, correct?
A. Yes, ma'am.
Q. And the McGary patent shows a detachable needle, correct?
A. Yes, ma'am.
Q. And the 3mL Integra has a detachable needle, correct?
A. Yes, ma'am.
Q. Okay. And, in fact, you can screw the detachable needle from the Saf-T-Med syringe on to the Integra syringe, correct?

A. Yes, ma'am.
Q. Okay. Now, I'd like to go to slide D62, please.
Now, the Saf-T -- this is the Saf-T-Med syringe needle assembly, correct?
A. Well, it certainly looks like the components, sure.
Q. Okay. And on the other side, we have the components of the Integra 3mL needle assembly, correct?
A. Yes, ma'am.
Q. The Saf-T-Med needle assembly has four parts, correct?
A. Five, counting the adhesive.
Q. Okay. But it has an outer hub, correct?
A. Okay. Sure.
Q. Right here (indicates)?
A. Sure.
Q. It has an inner hub, correct?
A. Yes, ma'am. That one is a snap-in one.
Q. It has a spring, correct?
A. Yes, ma'am.
Q. And it has a needle, correct?
A. Yes, ma'am.
Q. And you said it was a snap-in one?
A. Yeah. That's -- that doesn't boing-boing.

That snaps hard in.
Q. And the Integra has an outer -- the Integra also has four parts, right?
A. Yes, plus the adhesive.
Q. And it has an outer hub, correct?
A. Yes, ma'am.
Q. An inner hub, correct?
A. Yes, ma'am.
Q. A spring, correct?
A. Yes, ma'am.
Q. And a needle, correct?
A. Yes, ma'am.
Q. And in both the Saf-T-Med syringe and the Integra syringe, the hub snaps into the outer needle-holder, correct?
A. Say that again.
Q. Okay. In -- in both the Integra syringe and the Saf-T-Med syringe, the hub -- the inner hub snaps into the outer hub, correct?
A. Broadly speaking, yes. The Saf-T-Med, though, goes permanently in flush, whereas in the Integra 3mL, it has that spring disk in them, so that's that little boing-boing. So there's that difference and others there.
Q. Now, to retract a needle in the Saf-T-Med

syringe, the cutter cuts through the plunger seal, correct?

A. To retract syringe -- I'm sorry.

Q. To retract the needle in the Saf-T-Med syringe, the cutter cuts through the plunger seal, correct?

A. Well, I presume it does. I've never been allowed to activate one. But I understand that's how it works.

Q. And in the Integra syringe, the cutter cuts through the plunger seal, correct?

A. That's for sure.

Q. And in the Saf-T-Med syringe, after the cutter cuts through the plunger seal, it cuts through the inner needle hub, correct?

A. In the Saf-T-Med?

Q. Yes.

A. That's -- that's fine. Sure.

Q. Okay. And in the Integra, after the cutter cuts through the plunger seal, it cuts through the inner hub, correct?

A. Yes, ma'am.

Q. Now, in the Saf-T-Med syringe, after retraction, the outer hub is still threaded to the barrel, correct?

A. Sure.

Q. And a portion of the inner hub is still in the barrel after retraction, correct?

A. A portion of what you term the inner hub is still -- yeah, sure.

Q. And in the 3mL Integra, after retraction, the outer hub is still threaded to the barrel, correct?

A. Yes, ma'am.

Q. And a portion of the inner hub that you call the retainer member is still clamped in the barrel, correct?

A. Yes, ma'am.

MS. PIROZZOLO: Now, I want to put up Slide D63, please.

Q. (By Ms. Pirozzolo) On the left, we have a picture of the Saf-T-Med plunger, correct?

A. Yes, it looks familiar. I've --

Q. I --

A. I'm sorry. I haven't seen it too many times, but, yes.

Q. And on the right is a copy of the -- is a picture of the Integra plunger, correct?

A. That is correct. That's the inner -- inner plunger rod.

Q. The inner plunger.

Now, the Saf-T-Med plunger has holes in it, correct?
A. Yes. I believe upon inspection, there were two; one there and one on the other side.
Q. Okay. So here's the hole (indicates). And the Integra syringe has a core pinhole in the plunger, correct?
A. It has holes. Once again, they're core pins, support holes, or vents. The core pin is the large pin that goes this way (indicates). It's terminology, but it has a hole.
Q. This -- this has a hole?
A. And that has a hole.
Q. Now, you gave the opinion that sealing the needle-holder and spring in the syringe was an aspect of Mr. Shaw's invention; is that right?
A. Sealing the...
Q. You talked about the seal in Mr. Shaw's invention. Do you recall that?
A. Right. That it's a one-piece seal-and-release feature.
Q. Fluid seals were known in the prior art, correct?
A. Oh, sure.
Q. Mr. Shaw didn't invent fluid seals, correct?

A. No, he did not.
Q. Okay. And releasing a spring to retract a needle was known in the prior art, correct?
A. Of course.
Q. Interference fit between parts was known in the prior art, correct?
A. Yes.
Q. Now, you gave the opinion that the Integra syringes use Mr. Shaw's method of sealing and opening the plunger, correct?
A. Of -- of sealing and opening the plunger?
Q. Yes.
A. Well, broadly speaking, sure.
MS. PIROZZOLO: I want to put up Figure 1 of the '733 patent.
Q. (By Ms. Pirozzolo) First of all, you agree that this is Figure 1 of the '733 patent?
A. Yes, it's Figures 1 and 2.
Q. Okay.
MS. PIROZZOLO: I want to zoom in on this portion of Figure 1.
Q. (By Ms. Pirozzolo) Now, in Figure 1, there's a stopper at the end of the plunger, correct?
A. That's correct. I -- yes. It might be called a plug, but, yes.

Q. And that's No. 42; is that right?
A. Yes, ma'am.
Q. The plunger in Figure 1 of the '733 patent also has a seal, correct?
A. Sure.
Q. Okay. And the seal is -- we put it up in blue -- is No. 36, correct?
A. That is correct. That's the non-movable field.
Q. Okay. And the seal is not the same as the stopper, correct?
A. Right. And the plunger, sure.
Q. Okay. Now, in the Integra syringe, there's no stopper, correct?
A. No separate stopper, no.
Q. There's only a seal on the end of the plunger, correct?
A. There's a one piece -- one piece of rubber that serves both purposes.
Q. Now, during your direct testimony --
MS. PIROZZOLO: I'm going to put up --
Q. (By Ms. Pirozzolo) You referred to Plaintiff's Exhibit 351, correct?
A. I remember the number.
MS. PIROZZOLO: Can we go to Page 2 of

that exhibit?
A. Oh, I remember.
Q. (By Ms. Pirozzolo) Yes. You -- you talked about this page, and you said it supported your conclu -- opinions of copying, correct?
A. Yes, ma'am.
Q. Now, I want to focus in on -- well, let me -- let me review.
So this is the plunger of the VanishPoint, correct?
A. Well, that's a representation of it. It's a BD document, so I have to trust them that it's an accurate representation. But that's what it says it is.
Q. And this is a representation of the plunger in the Saf-T-Med product, correct?
A. Yes.
Q. And this is a representation of the plunger in the BD Integra syringe, correct?
A. Yes, ma'am.
Q. Now, I want to focus on this part of Exhibit 351, Page 932.
A. Yes, ma'am.
Q. Do you see the note there that says bad?
A. I do.
Q. Okay. People don't copy something they think

is bad, do they?

A. No, they don't. There's an explanation, but I'll wait.

MS. PIROZZOLO: Now, I also want to look at Page 324934 of Plaintiff's Exhibit 351.

A. Sure.

Q. (By Ms. Pirozzolo) That's the third page of the document, of Exhibit 351, correct?

A. Okay.

Q. Okay. And this page has three points of comparison of spring-based syringes, correct?

A. Yes, ma'am.

Q. Okay. The first point is how they store energy for retraction, correct?

A. Yes.

Q. And there it shows the BD syringe, Saf-T-Med syringe, and RTI syringe all use compression spring, correct?

A. Yes, a steel one at that, a stainless steel one, frankly.

Q. The next point is a comparison of how the different syringes release energy for retraction, correct?

A. That's what it says.

Q. The BD syringe releases the cutter from back side of stopper, correct?

MR. HARDIN: Your Honor, I just want the jury to be aware that the same instruction you read a moment ago about product-to-product comparisons applies to this slide.

THE COURT: Any response?

MS. PIROZZOLO: I think -- I think you've given the instructions.

THE COURT: Very well.

Then this line of testimony also is covered by Limiting Instruction No. 1.

Q. (By Ms. Pirozzolo) The BD syringe releases energy for retraction with a cutter from backside of stopper, correct?

A. If there -- is that the 3ml? I don't know.

Q. You relied on this document, correct?

A. No -- sure, sure.

But in the 3ml, it comes from one side of the stopper. In the 1ml, it comes from the other side. So just for clarity's sake, I'm going to assume this is the 3ml.

And so the cutter comes from the back side of the stopper, sure.

Q. In the Saf-T-Med syringe, cutter comes from back side of stopper, correct?

A. Yes. Yes, ma'am.

Q. And in the RTI syringe, it's an elastomeric ring around hub, correct?

That's what the document says, correct?

A. That's what the document says, sure.

Q. So this document makes clear that the method of releasing energy for retraction in the BD and Saf-T-Med syringe is the same, correct?

A. Yes, ma'am.

Q. And that the BD syringe is different from the RTI syringe, correct?

A. From the commercial embodiment of the RTI syringe.

Q. Now, the third point of comparison is the open retraction path, correct?

A. Yes, ma'am.

Q. Okay. And this says BD cutter core stopper, correct?

A. Yes, ma'am.

Q. Saf-T-Med cutter core stopper, correct?

A. Yes, ma'am.

Q. RTI elastomeric plug in plunger rod, correct?

A. Right. Plug, yes.

Q. So BD and Saf-T-Med are the same, correct?

A. Yes, ma'am.

Q. And they're both different than RTI, correct?
A. From the commercial embodiment of RTI.
MS. PIROZZOLO: I have no further questions.
THE COURT: Redirect.

REDIRECT EXAMINATION

BY MR. HARDIN:

Q. Mr. Sheehan, on those last points --
MR. HARDIN: Could I ask that that same exhibit be redisplayed, the -- and the one with the plunger -- I think it was 63 -- no, I'm sorry.
THE WITNESS: 351.
MR. HARDIN: The 351.
Q. (By Mr. Hardin) While they're finding that -- while they're finding that, there was -- that's the one where there were -- there were three plunger rods and over -- over the RTI one, it said bad, and Counsel pointed out that it said bad.
A. Sure.
Q. Do you understand the technology in this case well enough to understand what that -- what that refers to?
A. Absolutely.
Q. What is that?
MS. PIROZZOLO: Objection, Your Honor.

MR. HARDIN: Your Honor, she --

THE COURT: What's the nature of your objection?

MS. PIROZZOLO: Speculation.

THE COURT: Why don't you provide a foundation as to why -- you can renew your objection, if you feel there's not a proper foundation.

MR. HARDIN: Okay. All right.

Q. (By Mr. Hardin) In addition to the -- in addition to the patented features here that we're talking about --

A. Yes, sir.

Q. -- are there other considerations in the syringe, other than merely how it operates, other considerations that might be commercially desirable?

MS. PIROZZOLO: Objection, Your Honor.

THE COURT: Overruled.

A. Certainly. There are a number of them. The primary one that comes to mind is the issue of something called dead space.

Q. (By Mr. Hardin) And dead space is that small amount of fluid that might be left in a syringe if the -- if the -- if the way that it's designed left a little extra space at the end of the syringe?

A. That is correct. Comparisons are made amongst syringes regarding, oh, how much dead space there is. Happily now, there's a standard and everybody meets that standard. And folks that make flu vaccine always put a little bit extra in the vial to make sure that you can get 10 full doses, allowing for the dead space.

Typically, there's dead space in the needle.

Q. Okay.

A. So that's -- that's --

Q. And so a comment on a drawing like that might be indicating that we need to -- this should be reduced in some way?

MS. PIROZZOLO: Objection, Your Honor.

THE COURT: Overruled. I'll allow him to answer.

A. Yes. That's my understanding based on that, and I think surrounding documents, that that was what they were saying was bad.

Q. (By Mr. Hardin) Okay. Now as to the operation, however, let's talk about not just a commercial fine tune. Let's talk about how this operates, okay?

You testified that in this 351, the plunger handle on the RTI syringe as shown there, which fits the patent in the sense that it's the seal at the front, the thing that pushes the medicine, is fixed; is that

correct, first?
A. That's correct. The seal is fixed.
Q. Okay. And the -- and the fact that -- and it can't slide back when you're pressing medicine out?
A. That's correct.
Q. And that's so that you can withstand those kinds of pressures that you messed up the wall with the other day?
A. That is absolutely correct.
Q. Okay. And is that the kind of seal that Becton Dickinson put in its -- where it says stopper, is that the kind of seal they used in their product?
A. Yeah. They used the same kind of stopper in that regard as is in RTI.
Q. One that wouldn't slide back when you pressed the plunger rod?
A. Correct.
Q. Okay. And what about the center one, the Saf-T-Med one? How did it operate?
A. Well, it operated by collapsing. There were a number of -- number of little tabs. It says breaking tabs. They call them coupons in the patent.
But those tabs were supposed to break at a certain force so as to collapse and then activate, allow the cutter to go through and do what the cutter does.

And that's -- personally, I think that's not a very good design. And that design from Saf-T-Med did not find its way into the BD Integra product.
Q. Okay. Instead, they used a fixed seal to help with this pressure problem?
A. Correct.
Q. Okay. And that's why you think this slide shows using Mr. Shaw's design rather than the Saf-T-Med design?
A. Correct.
Q. Okay. Now, I'll move back to yesterday. I'm sorry, but we're going to go back very quickly to some things that were covered yesterday afternoon.
A. Sure.
MR. HARDIN: Can I have Figure 8 from the patent?
Q. (By Mr. Hardin) We talked about the issue of release; you know, what's -- what's being released.
Do you remember that?
A. Sure.
Q. We talked about clamping and friction and then what got released.
And the patent talks about what gets released in clamping -- clamping and friction, does it not?
A. It does.

Q. Okay. And in particular with respect to this Figure 8, is it true that in this figure, the needle-holder itself, which is that center portion right here (indicates) -- that's right.
Okay. That's being held via a force that's being transmitted through this bridge by this retainer ring which is up against the wall?
A. That's correct.
Q. Okay. So the force that's holding that needle-holder in place is being transmitted through that bridge?
A. Right. Transmitted through the bridge, and thus keeps the needle in the projecting position.
Q. And what happens when that bridge is cut or fractured or broken?
A. The needle-holder retracts.
Q. Are those forces released?
A. Absolutely.
Q. Now, let's look for a moment -- was this explained by Mr. Shaw in his patent?
A. Yes.
Q. Okay. Let's look for a moment at Column 9 of this patent.
Okay. This is from Column 9, and he's talking about any tack weld connecting the separable parts. The

separable parts are the non-retractable part, the retainer and the needle-holder.

A. That is correct.

Q. And he's talking about a tack weld that -- that -- the path of bridging portion, so he's talking about the bridging portion that connects the two of them, correct?

A. That's correct.

Q. Okay. Is ruptured, fractured, or otherwise separated, cut, so as to separate retainer ring 66 from inner head 72a, thus releasing needle-holder 22 from further restraint.

Is that the release that he's talking about?

A. Precisely.

Q. Does that happen in BD's product?

A. Yes, sir.

Q. Is there anything about the term, retainer member, that says that it can't be left behind and left clamped or just setting in the nose of the barrel?

A. No.

Q. There's no definition that Judge Folsom has given that says that can't happen?

A. No. The only applicable portion is a non-retractable part.

Q. Okay. So in your opinion is the forces --

are -- the forces that are released in the BD 3cc Integra, are those forces the kind of forces that Mr. Shaw said needed to be released --

A. Yes, sir.

Q. -- in order to let the needle fly back?

A. Yes, sir.

Q. Okay. I want to talk about the second point. I want to talk about three points. That's one.

No. 2, nose. We talked about nose yesterday.

A. Yes.

Q. Now, first of all, is it up to you and I or the jury to look at a picture of a syringe and decide where we think the nose should start or ought to start?

A. It's determined by the actual -- the drawing itself. You can see where it is. And the Court has made constructions, interpretations, of those elements:

The nose, the transition zone, and the barrel that guides one of ordinary skill in the art.

And I as an expert can say what one of ordinary skill in the art would understand what those terms mean and how they apply to the BD product, either the physical product or the drawings.

Q. Well, let's just look at -- at Tab 4 of the jurors' notebook. The third definition down is a definition of the word, nose.

And it appears from cross-examination yesterday that Becton Dickinson's expert, Dr. Sibbitt, got a different definition for nose or at least thinks the nose starts in a different place on their product than you.

Do you remember that?

A. Yes, I do.

Q. There were different colored areas, and there was an argument about Mr. Sibbitt is going to say the nose doesn't begin until later, and you say the nose begins earlier, correct?

A. Yes, sir.

Q. Now, the definition that Judge Folsom gave for nose is the portion of the syringe at the injection end that has a reduced diameter relative to the barrel.

Is that consistent with what you told us the nose was?

A. Absolutely.

Q. And if Mr. Sibbitt -- Dr. Sibbitt comes and tells the jury that, no, you just ignore that reduced diameter and look farther down, look farther out, and let the nose start there, would that be consistent with what the Court has said the nose is?

A. No, sir. It would be inconsistent.

Q. And the importance of all of this is that the claim, the box we have to show that BD is inside of, requires us to show that the retraction mechanism is in the nose, right?

A. That is correct.

Q. And if the nose starts at the place where there's a reduction in diameter from all the rest of the barrel, is there retraction mechanism in the nose?

A. Absolutely.

Q. And, finally, you were asked -- third point.

You were asked if you did any tests as to whether or not those holes there -- sometimes they're calling them pin holes or molding holes, but they're vents; they're holes?

A. Yeah, core pin supports.

Q. Okay. So do those holes -- you said you didn't do any tests to see whether air passed through them.

A. At the time I was asked, that's correct.

Q. Okay.

MS. PIROZZOLO: Objection, Your Honor -- well, I'm sorry.

Q. (By Mr. Hardin) Was -- was there any real need to do any real scientific testing in your view on that point?

A. No. You can look at the dimensions. You can see that there's a path for the air to go.

And the Court's construction on vent is simply this: An opening -- and this is on Page 1 of Tab 4 -- vent is near the bottom, third from the bottom.

An opening that provides an opportunity or means of escape, passage, or release. And that's -- certainly, whether that's a core pin or a vent, does that.

Q. Okay. And, in fact, if you used -- if you took that device right there and blew through it, would -- would air bubble out the back?

A. Yes, it would.

Q. So air is going to pass through that?

A. Yes.

Q. Okay.

A. (Demonstrates.)

Q. That air is coming out those holes?

A. That's correct.

MR. HARDIN: I have no further questions, Your Honor.

THE COURT: Recross?

MS. PIROZZOLO: No further questions.

THE COURT: You may step down.

THE WITNESS: Thank you, sir.

THE COURT: Call your next witness.

MS. PIROZZOLO: Your Honor, we were going to take --

THE COURT: I apologize. At this time, I think the Defendant would like to use some of their interim statement time. And, obviously, the Plaintiff can reply, if they so wish.

Up to five minutes.

THE WITNESS: Leave this?

THE COURT: We'll have someone clear all this, I'm sure.

MS. PIROZZOLO: I wanted to take this opportunity to briefly recap what we believe are the key points of Mr. Sheehan's testimony on cross-examination.

The asserted claims of the '733 patent all require a retainer member. And the asserted claims of the '224 patent all require a continuous retainer member.

The Court has defined those terms in its claim construction order. And specifically, retainer member has been defined as a non-retractable part of the retraction mechanism that uses some clamping or frictional force to keep the needle in the projecting position until that clamping or frictional force is released.

Given the Court's claim construction, as

Mr. Beck said during his opening, there are two questions to decide in this case.

First, do the BD syringes use clamping or frictional force to hold the needle in a projecting position; and, second, is that frictional force released when the needle in the BD syringes is retracted?

On the first question, we believe that the evidence shows that the needle in the 3mL Integra syringe is not held in -- in its projecting position by clamping or frictional force.

The inner hub and outer hub of the Integra 3mL needle assembly fit together with a snap fit. And you heard Mr. Sheehan admit on cross-examination that this was a snap fit between these two pieces. That's not a frictional hole.

This needle assembly is then screwed into the barrel of the Integra syringe with interlocking threads. You heard Mr. Sheehan admit that he has never seen interlocking threads like a screw characterized as a frictional hold in a textbook or a trade journal.

Finally, the clamping force that Mr. Sheehan identified between the outer hub and the barrel of the Integra 3mL syringe is not needed to hold the needle in a projecting position, because the needle is already projecting out of the needle assembly before it's even screwed into the barrel.

On the second question of when -- whether frictional forces are released when the cutter cuts through the inner hub of the Integra 3mL syringe, we also believe it is clear -- that the evidence establishes there is no release of those forces.

And I want to actually point to the movie that Mr. Sheehan prepared -- excuse me -- which shows you can see the retraction, and you can see that the threads -- the interlocking of the threads has not changed. They don't move during retraction.

So there's -- there's no release of frictional force, we believe.

And you can see that the piece that Mr. Sheehan has referred to as the retainer member is still clamped, and there is no -- has been no release of the clamp -- of the clamping force after retraction.

Similarly, in the Integra 1mL product, we believe the evidence shows that there's a mechanical hold between the bumps on the inside of the barrel and the groove in the needle hub. And although Mr. Sheehan estimated the frictional hold, he did not determine the amount of the mechanical hold versus the frictional hold.

And in addition when the cutter cuts

through the needle hub, the piece that Mr. Sheehan calls the retainer member, he admitted is still held with frictional force. So there is no release of frictional force in the Integra 1mL syringe, we believe.

Thank you.

THE COURT: Plaintiff desire to use any reply?

MR. HARDIN: Like two minutes.

If -- if Becton Dickinson could rewrite our property line, that might be right what she said. But that isn't the property line that we got from the Patent Office or the Judge has given to us.

Notice what she said. She said that the retainer ring, the thing that's clamped into the barrel, doesn't move.

There's no requirement in Mr. Shaw's patent that it move or not move. It's a non-retractable part.

What this case is about is what gets released. And what gets released is the needle. It flies back up into the barrel.

So they'd like to focus you on that outer part and say, well, that doesn't move. Look at the claim carefully. Look at the -- look at the boundaries that the Judge has helped us set for Mr. Shaw's property, and you will see that has nothing to do with the case at all.

That's all I'm going to say. Thank you very much.

THE COURT: You may call your next witness.

MR. HARDIN: Your Honor, we're going to play by video --

THE COURT: If you recall during the preliminary instructions, I said from time to time you would hear or see deposition, see and hear by way of video deposition. And at this time, we're going to have such a deposition.

MR. HARDIN: Yes, Your Honor.

We're going to play clips, actually, from five depositions. They are all going to be short. They are all engineers, Becton Dickinson engineers who worked on developing the products.

So they're not coming to trial, but we took their depositions in advance, as the law allows us to do. And we have taken excerpts from those to show you that we believe will demonstrate to you that -- that the engineers that worked on the Integra product were well-versed in how to RTI syringes worked. They were well-versed in the problems they needed to solve.

And they were looking hard at our products, which is shown in our patent, while they were making their product.

And the other thing we think they will show is that they -- you heard in opening that they used Saf-T-Med; they used Saf-T-Med. I think these will show -- some of these clips will show that that simply is not the case.

They did -- they did bring Saf-T-Med technology in, but they pretty quickly threw almost all of it back out, except for the cutter.

The first deposition is a fellow named Mr. Michael Carter. Mr. Carter was the lead project manager on the 3-mil syringe. So it was that -- the bigger one, and that's the first one that they developed.

And two things -- a couple of things, when you see his deposition, I want you to consider.

One is, you remember Ms. Duesman indicated that the beauty about this invention is you can use it with one hand. You don't need three hands.

The Saf-T-Med product, as it came in, couldn't be fired with one hand. You needed two hands to fire it, because it worked too hard. It was just too hard. And Mr. Carter will tell you, if you listen carefully, that the only one that he knew about that was one-handed, after -- even with the Saf-T-Med in place, was the RTI product.

Secondly, he's going to tell you that essentially they threw out almost everything that -- that the Saf-T-Med design had and redesigned everything.

And of course, that he was well-aware of RTI.

I'm going to say that a little bit -- that's all I'm going to say about Mr. Carter. These others I'm going to give even a shorter, 30-second intro in between each one.

THE COURT: How long will these four depositions last?

MR. HARDIN: About 20 minutes, 20 to 24 minutes.

THE COURT: Mr. Potts, can you help us with the lights, perhaps.

LAW CLERK: 3?

COURT SECURITY OFFICER: 4.

THE COURT: Thank you.

(Video playing.)

QUESTION: When was the first time that you actually saw an operable device that was a retractable syringe?

ANSWER: I don't know. It had to be within late '98, somewhere.

QUESTION: Okay.

ANSWER: But it's when they came to us -- whenever they came to us and asked us to do this -- this month-long thing.

QUESTION: And what was that product that they showed you?

ANSWER: I'm not sure.

QUESTION: Do you know whether it was a Saf-T-Med device?

ANSWER: At some point, I remember seeing Saf-T-Med and RTI syringes together. I don't know if that was the first -- first day or the first time I had seen one.

QUESTION: At the start of the project, you do recall that you had an RTI VanishPoint retractable syringe?

ANSWER: I had seen it before.

QUESTION: And do you recall how it first came to your attention?

ANSWER: Like I said, I think it was at the start of the project for -- for me, my involvement of the design effort around the Saf-T-Med days.

I think that was my first -- you know,

like I said, I had been working on catheters and scalpels. It was like my first exposure to safety syringes, and this is how -- you know, what the business is.

QUESTION: Okay. Do you recall who -- how you obtained it, who brought it to you?

ANSWER: No, not specifically.

QUESTION: Was it a 3cc syringe?

ANSWER: I have no idea. Probably. All our prototypes were a 3cc, all the Saf-T-Med ones.

QUESTION: Let's talk about -- let's talk about the product that you developed.

You ended up being one of the lead developers of the Integra product, correct?

ANSWER: Yes.

QUESTION: And when folks would have to fire the Saf-T-Med using two hands, you'd agree that there would have to be a grip change involved, correct?

ANSWER: If -- if a person had to add a second hand, that would be a grip change.

QUESTION: And that product, there was no end to the barrel to tuck the thumb pad into?

ANSWER: Right. There's no -- this area (indicates).

QUESTION: Okay. So at the time that you

started work on your project, is it true that the only product that you're aware of that could retract a needle directly out of the patient using spring force was the VanishPoint syringe?

ANSWER: That's all I can recall today.

QUESTION: Okay. And was it the only product at the time you started your project that allowed that spring force to retract and allow the patient to be triggered with the force of one thumb?

ANSWER: I -- I guess so. The retracting from the skin was a problem for us, so we never looked to see what -- what it did or why one did it.

QUESTION: Okay. Okay. At your later meeting with Mr. Jentzen, did you discuss any of the parts that are on this piece of paper?

ANSWER: Yeah. There was -- he was the technical guy that Erbs wasn't, so we discussed them all in detail.

QUESTION: And are there any of the parts on this piece of paper that you did not redesign when you created the Integra product?

ANSWER: No.

QUESTION: So all of the parts had to be redesigned for the Integra product?

ANSWER: Yes.

QUESTION: That includes the spring; you used a different spring?
ANSWER: Yes.
QUESTION: And you used a different cutter?
ANSWER: Yes.
QUESTION: And a different -- different inner and outer hub?
ANSWER: Yes.
QUESTION: And different barrel?
ANSWER: Yes.
QUESTION: Different plunger; is that correct?
ANSWER: Yes.
QUESTION: Okay. And did the needle attachment, the way in which the needle would attach to the barrel, was that the same for Integra or different than the Saf-T-Med? Is it -- let me rephrase the question.
The Saf-T-Med product had a detachable needle. So does the Integra. Do they attach and detach using the same mechanism?
ANSWER: They both had -- they both had threads.
QUESTION: Are they the same?

ANSWER: No.

QUESTION: So that was also redesigned by your team?

ANSWER: Uh-huh. Yes.

QUESTION: Did you ever have any discussions with anyone at your team meeting regarding the actual percentage or -- or need for the change of needles? Was that just something you accepted?

ANSWER: We discussed it, but accepted it pretty quickly. I think it was -- like I said, everything is a -- is a compromise. The project leader -- as the project leader, you kind of weigh those -- the intensity of each of the people as we're debating these.

That one was clear, that Marketing would fight it to the death, so we accepted it pretty early on, I think, in work done on a detachment.

QUESTION: So by the date of this document, May 9th, 1999, does that indicate to you that there -- there was a green light, as far as exchange of information between your team and Saf-T-Med personnel?

ANSWER: Yes.

QUESTION: And do you recall any -- getting any new discoveries or new pieces of information as a result of that firewall coming down?

ANSWER: No. We -- we went to Austin and we met with Jentzen for several days, but no major revelations.

(End of video clip.)

MR. HARDIN: We can keep the lights dim, if that's appropriate.

The next deposition we're going to show you is Mr. Richard Caizza. Mr. Richard Caizza was the engineer for Becton Dickinson that actually designed what the barrel looked like, and he's sort of the person that put all the features on paper.

And in particular, I'd like you to listen to his testimony. Mr. Caizza isn't sure, but he thinks he's the person that decided to put the collar on the back end of the barrel.

The collar is the thing that we believe is importantly a part of Mr. Shaw's invention, because through use of the collar, you can reduce thumb pressure, because you don't have to lock in the barrel. You can just push that little head into the collar. And it wasn't on the Saf-T-Med.

And here's Mr. Caizza's testimony on the design, including that feature.

(Video playing.)

QUESTION: I have had the court reporter

mark and hand to you as RTI 46, what I represent to you is a commercial 3cc Integra syringe and needle produced to my firm in this litigation.

Can you confirm that that's what that device is?

ANSWER: This is a 3mL Integra, yes. Whether it is a commercial one or not, I'm not sure.

QUESTION: You're holding it in your hand. Can you point to where the collar is that you just said is something added?

ANSWER: This collar (indicates).

QUESTION: This collar (indicates)?

ANSWER: Uh-huh.

QUESTION: Whose idea was it to add that collar?

ANSWER: I don't recall specifically whether it was BD or Saf-T-Med.

QUESTION: You -- you were a designer on that product, correct?

ANSWER: I was, yes.

QUESTION: As a designer, was it your decision to put that collar on that product?

ANSWER: I don't recall if it was my decision.

QUESTION: Who else besides yourself at

BD was -- was involved in the design of the 3cc Integra?
ANSWER: In the complete design of the 3cc Integra, I would -- we had -- we had a team. We had a core team, a multifunctional team that had input. Whether it was design or -- or not, I can't be sure. I know I led the design, and I could have very well have put it on, but I can't be sure 100 percent that it was me.
But this is, you know...
QUESTION: So it may or may not have been you who made the decision to put that collar on?
ANSWER: Correct.
QUESTION: Did you have discussions with anyone else at BD about the decision to put that collar on?
ANSWER: Yes.
QUESTION: Who?
ANSWER: There was discussions within the team. There was discussions at Saf-T-Med.
(End of video clip.)
MR. HARDIN: The third Becton Dickinson engineer we're going to hear from very briefly is Mr. A. Hubert Yang. He worked for years on the Integra projects, and I think you'll hear him say that he always had access to a product that uses one part of Mr. Shaw's

patents, the VanishPoint syringe.

(Video playing.)

QUESTION: Could you please give your full name and your current employment position for the record?

ANSWER: Sure. It's Hubert Yang, and currently a staff engineer with Cordis Corporation.

QUESTION: Where did you go after that?

ANSWER: Then I went to Becton Dickinson.

QUESTION: Do you remember about what year that was?

ANSWER: 2000.

QUESTION: And what was your position when you first joined BD?

ANSWER: It was Senior Research and Development Engineer.

QUESTION: And what product were you working on at the time?

ANSWER: My first project was the Integra 3mL project.

QUESTION: And how long were you working on the Integra 3mL?

ANSWER: About five years.

QUESTION: Do you recall whether any -- do you recall BD ever acquiring samplings of an RTI syringe just in general?

ANSWER: Yes.

QUESTION: And when did that occur?

ANSWER: Through -- through the development of the Integra syringe.

QUESTION: And do you recall how those were obtained?

ANSWER: Yes.

QUESTION: And how was that?

ANSWER: Some would come in through the sales field, and then we would also purchase -- purchase them as well.

(End of video clip.)

MR. HARDIN: The next Becton Dickinson engineer you're going to see briefly from is Mr. Charles Bush. He was the engineer when they developed the 3ml version first, then they went to the smaller version, the 3mL Integra syringe. Mr. Bush was involved in that design.

And we questioned him about the fact of whether the -- the holding force is friction or bumps that's been in issue about friction or bumps.

And I think what you'll see in this testimony is, as a -- as a molding person, he, like Mr. Sheehan, knew if you make the bumps too big, you can't pull -- pull the core pin out.

When you put plastic around something and it's -- and it's -- then the plastic solidifies. If the bumps are too big, you can't get the piece of metal out that was -- that the plastic was poured around. So he talks about that.

And he also talks about the fact that the friction -- the size of the seal was made larger to be sure that they wouldn't get leakage, that there'd be a seal, which Mr. Sheehan has told you is really increasing friction.

(Video playing.)

QUESTION: Good morning, Mr. Bush. Can you please -- state your full name and place of residence for the record.

ANSWER: My name is Charles Lewis Bush, B-U-S-H, Jr. I live at 44 Broadway Lane, Fairfield, New Jersey, 07004.

QUESTION: What was your role in the 1ml spring-based syringe project when you first joined?

ANSWER: I was hired as the lead engineer to design a 1ml syringe using basically the platform of 3ml and miniaturize it, if you will, or shrink it down and develop a 1ml syringe.

QUESTION: Were you the lead engineer the

entire time you were associated with the project?
ANSWER: Yes. There was -- yes.
QUESTION: Was there a point in time where you took over another role as well?
ANSWER: Yes. I assumed the team leader role.
QUESTION: Were there any other aspects of the 3ml syringe, other than the use of a cutter and a spring, that you attempted to incorporate into the 1ml syringe?
ANSWER: Not that I know of, no.
QUESTION: The document also references an increase in the OD of the hub area.
Does that refer to the outer diameter of the hub?
ANSWER: The OD is the outer diameter. I don't know if it refers specifically to the seals. I mean, the seals were part of the diameter. You had to compensate for shrinkage, so it was one of the challenges we had to constantly measure.
As you mold parts, parts shrink over time. So you'd mold the part, and we'd do shrinkage studies to understand what would look good today and what size is the part, you know, 20 days from now, which is roughly the shrinkage time. So you had to do that.

You also had to take parts and put it into shelf-life studies. So you expose a product to temperature. So you had to constantly do this reiteration of changing sizes, making them bigger to allow for shrinkage, so that we make sure we end up with the final sizes we wanted.

That's part of the whole molding process and mold adjustment process.

QUESTION: And if you look at an engineering drawing for a product, is that -- the dimensions on that considered to be the final dimensions you're shooting for after shrinkage?

ANSWER: Yes. Your final part tolerances should be your tolerances on the print, yes.

QUESTION: So, basically, the method of molding the part results in some sort of limit on how large a bump you can create on the inside of the barrel.

Would that be a fair characterization?

ANSWER: Correct. That's general challenge in molding a certain size and features.

QUESTION: Could you turn to Page 12?

These slides are entitled R&D Product Improvement Areas. Was this a portion of the presentation that you were responsible for?

ANSWER: Myself and other R&D -- R&D

support team at that point and the manufacturing team.

QUESTION: On the top slide, the second to last bullet point references the hub OD being increased to address leak -- leakage observations.

Does that refer to the design study we were discussing earlier?

ANSWER: Although it doesn't seem to reference that specific study, yes, I would -- I would read -- read it as, yes, it's referring to the same leakage study. It's using the same terminology as to incorrect hub positioning being the issue for leakage.

QUESTION: And it goes on to conclude that the increase in OD will cause additional frictional forces to be felt during activation?

ANSWER: That's what it summarized, yes.

QUESTION: And what do you understand those frictional forces to be -- or where do you understand those frictional forces to be?

ANSWER: They were talking -- at this point, it's focusing on the OD of the hub, so I'm assuming that at this point, it's looking at a specific, I guess, force test that was done to -- in that previous study isolated the hub to the plunger -- or hub to the barrel. Excuse me.

And that increase of OD came back with

higher forces, so I'm assuming that's what determined that. That OD change by 1,000 gave additional forces.

QUESTION: You testified earlier about the way in which the hub is held in place prior to activation in the 1ml syringe.

Do you recall that testimony?

ANSWER: Yes.

QUESTION: And how -- could you explain for me how the hub is held in place prior to activation?

ANSWER: The hub and barrel have what we designed as this double -- double-bump technology or double-bump features. Basically, they're a series of rings that interlock with each other in order to hold the hub in place and to create a seal.

The philosophy was pretty straightforward and similar to what we looked at on -- take a look at things like Tupperware, same thing. You need interlocking or contacting points to create seals for water -- you know, prevent water leakage but to give you resistance for removal.

And that seemed to be, you know, good commercial idea to take a look at and see how it applied.

QUESTION: Prior to activation, is the hub held in place by frictional forces?

ANSWER: You have -- you have two interlocking -- you have interlocking features that touch each other.

The -- the interlocking was what holds it in place, but anytime two pieces touch, there's always going to be some level of friction, if you will. Just -- just physics. That's what it is.

QUESTION: So you're saying that while there may be some frictional forces present, because two surfaces are touching each other, that it's the interlocking nature of the mechanism rather than friction that's holding them in place?

ANSWER: The -- the interlocking of the bumps is what gives it the mechanical lock. The fact that two parts touch each other, by nature, is friction. I mean, the two parts touch, so you have to have some level of -- I use the term friction at times because they touch. But the design is based off of having interlocking bumps to hold it in place and to create seals.

That was the challenge: Hold it in place, create multiple contact points for a seal to form. And that's what the double-bump geometry gave us.

(End of video clip.)

MR. HARDIN: Lastly, we have Eric

Schiller, another BD design engineer. Mr. Schiller will testify first about the retainer in the 3mL Integra syringe. You'll remember it has sort of a flange that gets squeezed up or clamped inside the barrel.

And he talks a little bit about a radial seal. And what he's talking about is, when you clamp that thing up, it squishes out a little bit and radially touches the side of the barrel, which, of course, increases friction, in our view and, in fact, creates additional friction in the clamping forces to keep that needle in a projecting position.

Secondly, and interestingly, in opening, you heard that Becton Dickinson has holes in the plunger handle, but they're there because of molding purposes.

And Mr. Schiller -- you'll hear Mr. Schiller testify that he doesn't know of any facts that require those holes to be present for molding purposes.

And, of course, what they are really there for is for the use of vents so fluid doesn't come out the front, as Mr. Shaw first discovered, and as Becton Dickinson decided to use.

Here's Mr. Schiller.

(Video playing.)

QUESTION: Does the current Integra have

a radial seal at all?
ANSWER: It's got a tapered seal, so it's a portion axial and a portion radial.
QUESTION: And when you were talking about the taper, you were referring to the -- what are you referring to?
ANSWER: On the inner hub, there's a -- it's not flat. It's got actually a shape to it, a cone shape.
QUESTION: Okay. And that mates with that internal flange of the barrel?
ANSWER: Yes.
QUESTION: Which is also tapered?
ANSWER: Yes.
QUESTION: Okay. And that has some radial component to that seal?
ANSWER: Correct.
QUESTION: Do you have any knowledge about whether any tests were run to determine whether the core supports and inner plunger rod of the current Integra syringe were required for moldability reasons?
ANSWER: I'm not aware of any test that was performed.
QUESTION: Okay. So you've never seen or were told of any test reports that showed that such

mold -- such core supports weren't required?

ANSWER: I -- I think I was told at one point that the core pin supports weren't required, but I don't know if a test was ever performed or if data was ever generated.

QUESTION: Do you recall who told you that?

ANSWER: No.

QUESTION: Do you recall about when that might have been?

ANSWER: It would have been when I was first moving on to the project to understand what is Integra.

QUESTION: Would that have been something you would have discussed with the rest of the project team?

ANSWER: It's possible.

QUESTION: Do you have knowledge of any facts that would support a need for the core supports in the inner plunger rod of the current Integra syringe?

ANSWER: Facts, no.

QUESTION: And you testified a little while ago about the purpose of the -- about the core pin holes in the 3mL Integra inner plunger rod.

Do you recall -- do you recall that

testimony?

ANSWER: Yes.

QUESTION: To your knowledge, what is -- why are those holes in the inner plunger rod of the 3mL Integra?

ANSWER: To prevent the core pin from deflecting during injection of the plastic into the part --

QUESTION: I'm sorry. What?

ANSWER: The core pin from deflecting during injection of the plastic into the cavity, which would cause you to have a bowed plunger drive.

QUESTION: To your knowledge, did --

ANSWER: Bowed plunger drive.

QUESTION: To your knowledge, did those core pinholes have any other purpose other than what you just described?

ANSWER: No.

(End of video clip.)

THE COURT: Does that complete the deposition offer at this time?

MR. HARDIN: It does, Your Honor.

THE COURT: The lights.

Call your next witness.

MR. HARDIN: Retractable Technologies

calls Mr. Shaw.

THE COURT: Mr. Shaw, if you'll come around.

COURTROOM DEPUTY: Would you raise your right hand.

(Witness sworn.)

THOMAS J. SHAW, PLAINTIFF'S WITNESS, SWORN

DIRECT EXAMINATION

BY MR. HARDIN:

Q. Good morning, Mr. Shaw.

A. Good morning.

Q. Where do you live, sir?

A. I live in Frisco, Texas.

Q. And what is your current job?

A. I'm the CEO and President of Retractable Technologies.

Q. Where did you attend school?

A. Originally, I went to a high school in Tucson, Arizona.

Q. And where did you grow up?

A. I grew up in Tucson, Arizona.

Q. What did your dad do for a living?

A. My dad was a chemist, and then he became -- he invented nitrogen testing in plants, and then he became an agricultural consultant to help farmers improve their crops.

Q. Did you go to college?

A. Yes, I did. I graduated with a degree in civil and structural engineering from the University of Arizona in 1977.

Q. And did you -- how did you get to Texas from Arizona?

A. After I got out of school, I came to Houston to look for work.

Q. And did you eventually find work further north than Houston?

A. I -- I originally worked on some projects, and when that changed, I went to a new position as a designer for Delta Steel Buildings in -- up in Dallas.

Q. Did you continue your education once you got to north Texas?

A. Yes. I started going to night school until I -- in 1993, I completed a master's degree in accounting.

Q. Now, can you just briefly describe what you did in those first jobs before we get into what you invented in this case? What was your experience in those first early jobs as an engineer?

A. Well, I was a project manager. And as a part of that, I also designed some safety equipment. And then later, I had a job for Halsey Engineering. He had a grant to redesign the air distribution system for ventilating the E-2C airplane.

Q. Now, you said he had a grant. Did you become aware, during your work -- early work as an engineer, about a government grant program that would fund research and design?

A. Mr. Halsey had retired to work in a machine shop with his kids, and he had been -- had engineered at Esystems, and so he had submitted and obtained a small business innovative research grant.

And the way those grants work is you get -- it's in three phases. The first phase is to do a feasibility study. And the second phase is to reduce it to practice. And the third phase is then funded. That's for marketing the new technology.

And what I learned from that program is that most small jobs are created by -- most new jobs are created by small companies, and also most major break-throughs in technology come from new companies.

And so the government has this SBIR, they call it, grant program. And he had one of those grants, and he had me work on the system to try to help with the problems they were having in the first Gulf war with the computer components from lack of air distribution.

Q. Okay. Now, is there a time when you broke out from that employment and formed your own company?

A. Yes. After I received my registration in the State of Texas as an engineer, I opened my own business in Lewisville, Texas.

Q. Okay. And what was the name of that company?

A. It was called Checkmate Engineering.

Q. And what was the business of Checkmate Engineering?

A. We were just civil and structural engineers to provide services for the town of Lewisville, a town of about 15,000 people.

Q. So you -- did you check foundations and that sort of thing, like a -- like a normal structural engineer?

A. Foundations, site plans for TGIF at a mall area, or wrote designs, just whatever the town needed.

Q. Okay. Now we're here today because of your interest in syringe technology and inventing syringes.

When did you first start -- get an interest in that and start -- what's the year timeframe you started researching and inventing in the field of retractable syringes and similar devices?

A. That would be 1988, somewhere -- I don't recall specifically the day, but somewhere around 1988,

'89.
Q. And was there something that caused you to become interested in syringes and needlestick safety?
A. Yes. I was, late at night, before I went to sleep, watching television, and there was a female physician on a program in California, and she was saying that they were having all these needlestick accidents, and with AIDS and the potential hepatitis, that the industry wasn't responding, and she didn't think that was right.
Q. And so you were an engineer, and you decided to get involved?
A. Yeah. It seemed to me that maybe that wasn't right. And so the next day, I went to my pharmacist, Bill Clemons in Little Elm, Texas, and asked him to give me some syringes so that I could look at them and see what the problems might be.
Q. Okay. And just kind of leaping forward from that day till now, approximately how many different kinds of products have you invented that deal with needles or syringes over the last 20 years?
A. Well, there's -- between what's on the market now and what's about to be on the market, I would say 10.
Q. Okay. Those are products on the market?

A. Some of them are soon to be on the market.
Q. Okay. And how many patents have you been awarded in the field of syringe technology?
A. Just specific to syringes, about 15.
Q. Okay. And what about safety devices or sharps devices?
A. Total patents?
Q. Yes.
A. 40.
Q. And internationally?
A. 400.
Q. Okay. So for every patent you file in the United States, you also file those worldwide, and that accounts for the disparity?
A. Yes.
Q. Because there's a lot of other countries out there.
Okay. Have your inventive efforts made you money?
A. Yes, they have.
Q. And have you received dollars for your syringe-type inventions?
A. Yes. I've been -- I've been paid in multiple ways.
Q. Okay. So to back up, what was the first --

what was the first way you were compensated in any way for working on or designing syringes?

A. Well, originally, I did obtain one of those small business innovative research grants, Phase 1 and Phase 2, and out of that, I was paid hourly.

And then later, when I developed promising technology and started Retractable Technologies, there was a transfer where I give RTI an exclusive license. And at that time, I received a licensing fee.

And then after that, I received royalties.

THE COURT: Mr. Shaw, why don't you back away from the mic a little.

THE WITNESS: Oh, I'm sorry. Yeah, I'm sorry. I'm nervous.

Can everybody hear me?

Okay. Well, when I'm nervous, I'm too loud.

THE COURT: Well, it's sort of creating a ring kind of.

THE WITNESS: Yeah, I'm sorry.

A. Let's see. Where was I?

So then I received royalties where the -- the gross -- on gross sales, and my effective royalty rate is about 7 percent.

And then related to that, I also receive a salary to be the President and Director of RTI, and that makes needle products.

Q. (By Mr. Hardin) Okay. Now, in addition to that monetary compensation, have you ever personally received any awards for contributions to safer needle technology?

A. Yes, I did.

Q. Okay. Is there any of those that you received that you're particularly proud of?

A. Well, one was from the University of Arizona. They had their hundred-year centennial celebration, and I received a humanitarian award for my contributions to safety.

And then in Dallas Business Journal, gives out an award for healthcare hero, and I received that award.

And then also I was honored by being asked to come to the Oval Office when needle legislation was passed, and I received a pin that that safety legislation was signed by, and I was given that pin by the President of the United States.

Q. So is this what hangs on the wall in your office, Mr. -- Mr. Shaw?

A. Yes.

Q. And that's a picture -- there were other folks at this award ceremony; am I correct?

A. Oh, absolutely. Becton Dickinson was there, and also some other syringe makers.

Q. And this is the pen -- one of the pens that President Clinton used to sign the Needlestick Safety Act?

A. Yes. He thanked me, and also he gave me one of the pens that he -- for one of the capitals in his name.

In other words, he signs a different letter with each pen and gives them to people around, and with me, he gave me the -- for the capital J.

Q. Do you share a name with him?

A. My middle name, Jefferson.

THE COURT: Is this a convenient stopping point for a morning break?

MR. HARDIN: It would be, Your Honor.

THE COURT: Why don't we take our morning break. We'll be in recess about 15 to 20 minutes.

COURT SECURITY OFFICER: All rise.

(Jury out.)

(Recess.)

COURT SECURITY OFFICER: All rise.

(Jury in.)

THE COURT: Please be seated.

You may continue your direct examination.

MR. HARDIN: Thank you, Your Honor.

Q. (By Mr. Hardin) Just before the break, we had gone over sort of some of the things that have happened to you more recently or later in your career. I want to take you back to when you first started -- started your career.

Did you start out with the intent to keep your ideas for your own use and build a company and make profits that way?

A. No. I had a little company. I was responding to the problem of the accidental needlesticks, and I was hoping some way to come up with a solution.

Q. Did you contact manufacturers early on to see if they'd be interested in getting your solution out in the marketplace?

A. Yes, I did.

Q. But eventually, you wound up founding your own company, and it's in Little Elm, Texas.

A. Yes, that's correct.

Q. And how many people do you employ there, sir?

A. We have about 150, and then we have some part-time people.

Q. And what types of work goes on there in that -- in that plant in Little Elm, Texas?

A. Well, we take raw material and plastic pellets, and we start with that, and we mold it, and we make the parts, and we do the assembly.

And then we also do the packaging, the shipping. Design is done there. Research is done there. And we also do marketing and warehousing.

Q. All out of that one facility in Little Elm?

A. Yes.

Q. Now, are your syringes --

THE COURT: Somewhere in between the first mic position and the last one.

THE WITNESS: Okay. Does that sound all right?

Q. (By Mr. Hardin) I think that's better.

A. Sorry.

Q. Now, are your syringes made anywhere else?

A. Yes, they are. We also have syringes made in China.

Q. Okay. And today -- at the Little Elm facility today, as we're all in this courtroom, how busy is that plant?

A. Well, we're now to where we're making about -- 50 percent of what we sell is in Little Elm, and we're running three shifts, seven days a week, 24 hours a day.

Q. And why is that at this particular moment?

A. Well, unfortunately, the swine flu situation hit, and we got a significant portion of that contract, and so it's keeping everybody busy.

Q. Is that a government contract?

A. Yes. The government has a program to try to make these vaccines and syringes available for everybody who needs it.

Q. And do you have an understanding of why the government had any kind of preference for your product?

A. It's my understanding that they wanted a fixed needle, and they were also interested because we had really effective safety so that the care worker wouldn't get exposed.

Q. Okay. We're going to -- we're going to start just in a moment, because I think it's an interesting story. I'm going to take you all the way back to the beginning.

But before we go back to the beginning, there were some statements made in openings that are in these patents. These are your three actual issued patents. These are your pieces of property.

And Becton Dickinson put some statements and attributed them to you from these patents that they say essentially indicated that you were saying something to the Patent Office and something different here.

And I'd like to look at that first statement

before we go any further and tell your invention story.
Is that okay?
A. Yes, sir.
Q. Okay.
MR. HARDIN: May I see the first slide, please?
Q. (By Mr. Hardin) Okay. This is -- in your patent in Column 1, this happens to be the -- this is the '224, I think. This is the '224. And this is the statement, the paragraph that was -- a part of which, at least, was shown during your opening.
It's in a part of the patent that's called Background of the Prior Art, I believe; is that correct?
A. Yes.
Q. Okay. And what did you understand the purpose of this paragraph was when it was submitted to the Patent Office?
A. My understanding is, it was supposed to describe the problems that the prior art had had trying to resolve these issues.
Q. Okay. And the second sentence -- I've underlined the second sentence.
It says, Other problems with the prior art are dependence on flexing or breaking of internal parts by the plunger in order to release the retraction mechanism

and use of a diaphragm at the end of the plunger, which must be penetrated by a needle-holding member and spring.

Do you see that?

A. Yes.

Q. And did you understand, at the time you began your -- making your inventions and working on these patents, that that had been a problem with the prior designs?

A. Yes. It had been a problem in trying -- in the way they had been doing it, they had not been able to deal with how to resolve those issues.

Q. Did you, during your inventive process, figure out a way to deal with any of those issues?

A. Yes. I -- on the breaking, I worked out a way of doing the breaking, so things wouldn't get hung up, and I -- if you look at my '733 patent, we've got small pieces, and I've learned -- I figured out a way to work with those small pieces and -- and with high-speed assembly.

And so throughout my designs, I figured out ways that to -- to master how to -- how to handle those problems differently than in the prior art so that they actually are manufacturable.

Q. Okay. Let's take a look at another piece of your patent you're talking about; not what other designs did before you, but actually your design; a part of the patent that talks about flexing or breaking.

Okay. Now, this is actually kind of deep into the patent where you're talking about -- you're referring to numbers and referring back to drawings about your designs, correct?

A. Yes.

Q. And you say, Any tack weld connecting the separable parts at the bridging portion is ruptured, fractured, or otherwise separated so as to separate Retainer Ring 66 from inner head, thus releasing needle-holder from further restraint.

Now, you did -- are you describing there how you dealt with the problem of rupturing, breaking, or fracturing?

A. Yeah. Yes, sir. By doing it the way that I did it, it was -- you were able to accomplish it without anything getting hung up on the -- on the area that's ruptured.

Q. Okay. Let's take a -- just a quick look at the figure that this -- these numbers are referring to one of the figures in the patent, and we've colored it in. This is the Figure 8 from your patent.

A. Yes.

Q. Okay. And is the -- the blue portion is what we've been terming the retainer member. That's what the patent calls it?

A. Yes.

Q. And the yellow dot -- we've made it a dot, but it's -- in the patent, it's shown as a small weld between -- which is what we're calling the bridging portion?

A. Yes.

Q. And the red is the needle-holder?

A. Yes.

Q. Okay. And the place where it was being fractured or separated to release is right at that bridging portion?

A. Yes.

Q. Okay. Now, I want to show you another slide from opening just briefly.

Now, in this same patent -- in all of these patents, you have three designs we talked about. We didn't really talk about the third one, but the two that we've been talking about are two separate designs, both of them in your patent, correct?

A. Correct.

Q. Okay. And the one on the left uses -- I think you sometimes refer to as a friction ring?

A. Yes.
Q. So that's where the retainer is not connected in any way and doesn't need to be broken?
A. Correct.
Q. Okay. And the one on the right has this bridging piece in between the outer ring and the needle-holder?
A. Yes.
Q. And is it your allegations in this lawsuit that Becton Dickinson is using your piece of property that's shown over there on the right?
A. Yes. They're -- they're -- the one on the right where you break through that bridge in order to release that friction that's held on the out -- it's being held on the out -- inside barrel wall by friction, is what's holding that thing from going back during use. And then afterwards, that -- the plunger -- front end of the plunger operates to break that, and then it's -- released that friction so that the needle-holder can be released up into the back.
Q. Okay. So now I want to step back. Let's sort of -- just to respond to some things said earlier in the case, but now I think this Court may be interested in taking you back to sort of the start of this process. We're going to do that sort of it in stages.

First, before we go all the way back to when you first actually worked on the project, let me ask a general question. You have about how many U.S. patents in this syringe -- in the safety syringe field do you have?

A. About 15.

Q. Okay. And do all those patents use the same basic mechanics to retract the syringe?

A. There's actually two different families of -- all of them are automated retraction devices, but in the early group, I had a rod that pulled the needle up into the handle where I had an elastomer spring.

And then the later improved versions, I moved the spring to the front and pushed the needle all the way up. But they're all automated retraction.

Q. Okay. Now, the one where the spring was in the front, what was the earliest patent you received on that type of design rather than having the spring in the back?

A. That -- that would be, I think, the '551 in September, maybe, '93.

Q. Okay. Can we see just briefly -- is this a drawing from that patent?

A. Yes, it is.

Q. Okay. And the spring is in the front in this design?

A. Yes.

Q. This is the spring right here (indicating). And is this a retainer member here?

A. Yes. That -- that's the retainer member that's being slidingly held in friction on the inside wall of that -- of the barrel.

Q. Okay. Is this patent in issue here in this case?

A. No, it isn't. It is the first time in my technology where I showed that sliding frictionally held ring on the inside, but later, I developed improvements on that, including the bridging portion, which is the reason we're here.

Q. Okay. And did you make any prototypes or products that could be tested using this early design?

A. Yes, we did. We made thousands of them and tested them.

Q. Okay. Now, I'm going to just briefly ask you some real brief questions about these actual pieces of property, because you're the owner of these pieces of property, and we need to establish that for sure. And then we're actually going to get to your invention story. I misspoke a minute ago. I think we need to do this first.

The first patent that I want to direct your attention to is the '224 patent. And are you the named inventor of this patent?
A. Yes, I am.
Q. And have you owned this patent since the date it was issued by the United States Patent Office?
A. Yes.
Q. And did you exclusively license this patent to Retractable Technologies?
A. Yes, sir, I did.
Q. And since shortly after it issued, have all the VanishPoint products that use the technology have the patent number marked on their packaging?
A. Yes, sir.
Q. And what is your general understanding of the '224 patent, just briefly?
A. Well, the '224 patent basically addresses the mechanical and hydraulic problems of making a retractable syringe. It has the retainer in it for the releasing the needle-holder that's frictionally held on the inside part of the wall. And then it shows two versions of it, a bridge version and a non-bridge version.
And then in addition to that, it has a barrier so that when you go to give the injection, you don't

drive the needle further into the patient. And so that acts as a stop.

And then very importantly, it also has a rigid -- rigidly fixed seal around the plunger handle so that that seal can't collapse during injection and blow out prematurely.

Q. Okay. And one of those --

MR. HARDIN: Can I have the next slide, please?

Can you blow that up?

Q. (By Mr. Hardin) So one of the alternate constructions, again, in this claim was this use of the bridging portion where the -- where the -- an alternate construction of the two-part head of the needle-holder comprises separable retainer member being welded to the inner head of the needle-holder, preferably along a small ridge or bridge between the mating surfaces, which holds the two-part head together until the bridge is ruptured by movement of the plunger after injection has occurred.

That's what we've been talking about that you believe is the piece of property that has been trespassed -- trespassed upon?

A. That's the version with the bridging portion --

Q. Yeah.
A. -- that separates --
Q. Right.
A. -- that I believe they are using.
Q. Okay. But the real test for that, again, all of those claims we went through, this is just a reference to that in the -- in the patent?
A. Right.
Q. Okay. Briefly, the '077 patent, I'm going to ask you a similar set of questions about that.
Are you the named inventor on this patent?
A. Yes.
Q. And have you owned this patent since its issuance?
A. Yes.
Q. And did you exclusively license this patent to Retractable Technologies, Inc.?
A. Yes, sir.
Q. And since shortly after it issued, have all or substantially all of the VanishPoint products that use the technology in the '077 patent, have they been marked on their packaging with this patent number?
A. Yes, sir.
Q. Now, how do you understand the protection in general -- we know it's really the claims, but your

understanding as an inventor of what protection the '077 patent affords you?

A. Well, the automated retraction technology, whereas the '224 was more about the mechanical and the hydraulic problems, the '077 was to -- it really addresses clinical -- clinical needs in the sense that when the handle tucks in the back, it becomes its own sharps container. It's got -- it becomes -- the needle is within that plastic syringe.

And then also it had the venting to reduce the splatter, so when the healthcare worker finishes the injection -- I mean, she should go to the sharps box, but since the needle is retracted, if she accidentally puts it down or puts it in her pocket, there's not going to be splatter on it, and the handle is -- is going to be tucked safely in the back.

So it's more about safety for the clinician.

Q. Okay. And lastly, the '733 patent, similar questions. Are you the named inventor on this patent?

A. Yes, I am.

Q. And did you -- have you owned this since its issuance?

A. Yes, sir.

Q. And did you exclusively license it to Retractable Technologies?

A. Yes, I did.

Q. And since shortly after it issued, have all or substantially all of the VanishPoint products that use this technology have that number marked on their packaging?

A. Yes, sir.

Q. Okay. And briefly, what do you believe the technology is, in general, that is protected by this piece of property?

A. The -- this is the --

Q. The '733.

A. The '733 relates to making the product manufacturable. This is -- as I got to the manufacturing stage, then I made innovations to make it easier to assemble.

And this patent relates to being able to bring in the -- initially, the spring and then the needle-holder and slide in the retaining needle-holder into position from the back of the syringe using a one-piece barrel.

And then very importantly, you put the needle on afterwards, because in a one-piece barrel, you have this little hole in the front, and if you try to pass that needle through it, if it touches that needle, it will bend it, and it will hurt the patient, if it gets bent.

And so this is an assembly method where you could put the whole thing together quickly and inexpensively and then put the needle and glue it on later, so the needle point would never be touched.

Q. Okay. Thank you.

So now finally, I want to go back -- take you all the way back to the 19 -- you said you saw a TV show one night in '88 or '89.

A. Correct.

Q. And I think you said the next day, you went to the pharmacist and got some syringes, because you were curious about whether engineers could help.

A. Yes, sir.

Q. What did you do with those syringes?

A. Well, initially, I just started carrying them with me and looking at them to try to think about how difficult it would be -- at that time, I had no solution, I just had a problem, and that is, how is a healthcare worker going to give an injection and then be safe.

And so I just started spending time and reading and doing some research.

Q. Okay. Did you consider just trying to shield that open point somehow, just put some kind of a cap or shield -- move a cap or shield over it?

A. Yes. I did think seriously about trying to come up with some kind of a sheathing mechanism so that with the needle still extended, you could somehow cover it after use.

But when you normally give an injection, it's one-handed, and I just couldn't -- I was concerned about bringing the other hand over, because if you're not watching carefully, then the other -- it seemed to me the other hand would make it more dangerous.

And so the sheathing was -- I thought would be probably not a good idea.

Q. And do you recall when you decided that in order to really be safe, you had to get this automatic retraction, the needle coming automatically back up into the barrel?

A. Well, I was fishing and -- with my nephew, and we went through about a two-hour discussion about all possible ways of sheathing, and everything required at least a grip change where you might drop it.

And finally, at the end of that, I just decided once and for all that it just had to be automatic -- automated retraction where the needle just disappeared without having to change the user's hand position.

Q. Now, once you decided on retraction and you're looking at it with an engineer's eyes, what obstacles did you see to making that happen, to have that needle come back up into the syringe body?

A. Well, once you decided you're not going to have the needle fixed on the end of a syringe barrel, like it's always been in the past, you've got -- you've got a serious problem, because you're going to have to have some kind of seal around the needle.

You heard the other day about the fluid pressure being three or four times a garden hose. So if you don't have a really tight seal around that needle, that fluid, instead of going through the needle, is going to leak and go around it.

So if you've got that seal real tight around the needle and you go to release the needle, the seal is not going to let go of the needle. And so you've got that problem.

And then in addition to that, you've got your needle-holder, and what are you going to do to release that?

And so you've got -- and you have to have some way to retract it out of the patient.

Q. And what about the thumb force? Did you consider about that -- consider that?

A. Well, on your -- on your thumb force, you've got -- yeah, the two things go against each other, and I think that's what made the project so difficult.

You've got this real high hydraulic force. If somebody has a real strong thumb, like a golfer -- we did some tests, and some people can push up to 18 pounds, but other people can only push up to about 9.

And so you've got some people that have to be able to retract it at 9, but you've got other people that might give an injection at 18, and then the fluid would rupture or pre -- pre-retract it before you were done.

And so you had -- how are you going to have this fluid pressure that's going to allow you to go to 18, but you're going to have to have a mechanical release that's going to operate at 9 pounds.

And so the challenge is how to accomplish both things within the same device.

Q. Is that sort of a force/balance question or issue?

A. Yeah.

Q. Okay. Now, what about changing the size of the barrel of -- I mean, you're going to put things inside the barrel to do all this -- has all this mechanical and hydraulic activity.

What about -- was there anything about the size of the barrel that was a limiting factor on that?

A. Yeah. Yes. And -- and if things weren't bad enough that you have to have it not fire at 18, but it has to fire at 9, the other problem is, is that because the increments on standard barrels have already been set for regular medications, and you can't change how close the increments are -- so you can't increase the diameter of the barrel.

So whatever solution you come up with is going to have to fit within the barrels that they already had.

So you have to work within those sizes.

So you're going to put in these hydraulic and mechanical pieces, but they all have to fit within a standard syringe. And on the 1cc, the thing is about the size of a pencil, so you really don't have much room to work.

Q. And what about materials? What about the different kinds of materials that you might be able to use to get all these features performing in a retractable syringe?

A. Well, that was just one more thing to add to an already almost impossible task, and that is that materials, when you give injections with different medicines, some of those materials can interact with medications, and all the chemicals and medications have been worked out for polypropylene plastic, and so you really have to stay with the same medical grade materials.

And then in addition to that, polypropylene plastic, if you ever handle a syringe, is kind of oily, so you can't glue the components, so everything has to be moldable into the final shape that you're going to use.

Q. Okay. So you're thinking about all of these things as an engineer. What did you start doing? How did you start on this project?

A. Well, the first thing I had to determine, in order to know if the world really could have a retractable syringe, is how much force is required to pull the needle out of the patient, and would a spring have sufficient strength to accomplish that.

And so initially, to get that force, I tried poking myself a few times and decided that was not a good way to determine that force. So I went to a butcher shop and bought different cuts of meats, and I stuck them with needles and tested them until I determined what that force was.

Q. So you just bought different cuts of meat and stuck them with a needle and used measurements to figure

out how much force it took to get it back out?
A. Right. And it was actually -- pig's feet had the skin that made it the most difficult to pull out. I tried different sections, because you have different uses of syringes.
Q. Now, what did those spring-force tests teach you?
A. Well, what I determined is that it was possible. If -- I -- I found a spring size that would retract consistently a needle out of -- out of the tissue.
But what I also determined was -- is that where you could get a spring to do it, in order to get the spring to fit in these little teeny barrels, about all the spring force you would get would be just enough strength to pull it out of the patient. It wouldn't leave any spring strength to do the -- to take care of the other forces that you had to accomplish.
Q. So what other forces did you need from the spring?
A. Well, I talked earlier that if you were going to have a needle, and it's not fixed on the end of the barrel, it's going to be going through a rubber stopper or seal, you're going to need the spring strength not just to pull it out of the patient, but now you've got

to pull the needle out of that rubber.

And rubber to steel is one of the highest coefficients of friction, and so there wasn't nearly enough force to pull it out of the patient and also pull it out of that seal that you were going to have to have in order to let that needle be released.

Q. So what did you decide early on about these designs?

A. Well, in my earliest design to solve that problem, what I did is, I mounted that needle in a rod so that -- and then the rod butted up against a seal, but the seal didn't actually touch the needle.

And so that allowed me to pull the needle out of the patient without having to pull the needle out of the seal. It just -- it just created a seal by butting up against it and separated it, but the -- the metal of the needle never touched the rubber of the seal.

Q. And did all of your designs and all of your patents and your prototypes, did they all have this feature of having a needle -- a metal needle mounted on either -- either a rod to pull it from the back or -- or a smaller needle-holder like we've seen pictures of in this case?

A. Yes. I carried that forward -- carried that forward into needle rods in my original designs and then later needle-holders. But we have never gone back and -- and tried to address pulling it out of the rubber. So all of our technology uses that concept.

Q. Okay. Now, how -- how were these early tests paid for?

A. I paid for them.

Q. So you were creating these prototypes yourself?

A. Yes. I had a little engineering business in Lewisville, and I made little prototypes, and I paid for them myself.

Q. And did you -- did you draw things on boards and doodle and -- while you were thinking about these designs?

A. Actually, in our Lewisville office, I had a blackboard -- I was also doing regular work as an engineer. I didn't have a grant initially. And so to help me try to work -- and I was also going to school, and it got pretty busy.

So I had a blackboard in every room. And so whenever I'd go in there, I'd go and draw and try to figure out how to do this problem.

Q. I think we may have a picture of that from the company's history. Is this a picture of one of those blackboard designs?

A. Yes, sir, it is.
Q. It's dated sometime in 1990, and it says Inventor Shaw. Is this one of the designs that you sketched out early on in the process?
A. I know it's a design. I'm trying to figure out which one it is. But it is a rod that pulls up from -- it's an early one.
Q. Okay. Now, by 1991, did you have a design you thought might work?
A. Yes. By 1991, I had managed to solve the sealing problem, and I had an elastomer in the back of the rod. And so I had something that I thought -- it would at least handle the seal and pull the needle out of the patient.
Q. Okay. And did you make one of those up, that design, after you thought about it?
A. Yes, I did. I made an oversized prototype, so I could see what I was doing. I made it big enough so that I could work on. So it was enlarged.
Q. Okay. Do you have PX 10 in the courtroom here up at the -- up at the desk by you?
A. Is it the prototype of that?
Q. Yes. Yeah.
A. Yes, this is it.
Q. Okay. Is that the actual one you made back in

about 1991?
A. Yes. And I have to say, compared to what we're doing now, it's pretty crude.
Q. Okay. But it was -- it was made large size like that so you, as an engineer, could see and figure out how it worked?
A. Yes, because I thought, if I could make it on a big size and refine it, then I could size it down in order to try to fit it in the little area.
Q. Okay. So you made that, but did you ever use it?
A. In a -- in a kind of indirect way. I went to Bonham, Texas, and had somebody use it on me. A doctor in Bonham gave me injections with this product. It didn't seem right to make something and have somebody else be the first one to try it, so I had it done to me.
Q. And did someone -- was someone there with a movie camera to record the event?
A. Yes. Since I couldn't see what was going on, since he was injecting me, we had somebody film it.
Q. Okay. I think we have that film from -- this is 1992?
MR. HARDIN: Do we have a problem playing the film?
(Demonstrations video playing.)

MR. SHAW: The purpose of us being here is we're going to demonstrate a nonreusable retractable syringe. The purpose of this particular demonstration is to show the retraction feature.

Can you see?

UNIDENTIFIED WOMAN: Uh-huh.

(Video stopped.)

Q. (By Mr. Hardin) Okay. What was in that injection you got?

A. A saline solution.

Q. Okay. Now, after those tests or around that period of time, did you file a patent on that design?

A. Yes, I did.

Q. And --

A. And that was in 1991, I believe.

Q. Okay. Now, having done that and having proven, at least to yourself, that the needle could be used to inject fluid and retract out -- out of the body, did you decide to find some source of additional funding?

A. I had already, earlier in 1990, gone back to the SBIR grant method that I had learned about from Mr. Halsey, because I knew that in order to mold -- if I was really going to be able to advance this project, I would need a grant.

And so I had applied for an initial one in 1990, and it had been -- they told me it showed some promise, but they had some -- they have a panel of doctors and people, and they gave me some input.

And so I addressed that and re-submitted it, and then ultimately, I did get the first phase of a 50,000-dollar grant.

Q. Okay. I think we have some documents that show those grant applications.

So those were the letters that you were submitting to the -- to the -- from, at that time, Checkmate Engineering to the SBIR to the National Institute of Health to try to get grants?

A. That's correct.

Q. And what happened to your grant request?

A. Well, they funded it.

Q. And was it funded for the full amount?

A. 50,000, yes.

Q. Okay?

A. Well, maybe -- I can't -- I think it was 49-something, but it was close to 50,000.

MR. HARDIN: Can we see the page of the funding grant?

Q. (By Mr. Hardin) Now, this was -- a committee reviews this process, right? Your grant request?

A. Right. What they do is everybody sends in grants from all over the country, and they all go to a hotel, and then they read them all, like in a weekend. And then they have -- if they pick out the promising ones and then they have a committee of biologists, doctors, materials people. And they read these grants, and they determine which ones are most likely to result in some type of technology.

Q. Okay. This says: In summary, the committee found this revised -- this was because you had revised the grant request -- application to be of excellent scientific merit and recommended that it fit -- that it be further considered in full, time and amount, for the consideration that was recommended, because the proposal is thorough and carefully addresses each of the shortcomings cited in the previous review, and the proposed investigative team is highly qualified. The committee expressed a minor concern about the proposed device. It's relatively -- relative complexity and the impact of this factor on reliability and cost competitiveness. This general consideration did not, however, detract significantly from the committee's overall high level of enthusiasm.

They were telling you it looked like you had a tough row to hoe, in short?

A. Yes. And I think they were also telling me with my award that I probably had already done some hoeing in order to get to that stage.

Q. Okay. Now, did you continue to make prototypes?

A. Yes, I did. And eventually, I took this monster syringe that I had injected myself with and reduced it down to the size of -- with the grant money, down to the size of the -- so the increments would be correct, down to a 3cc size.

Q. Do you have a copy of that prototype or, in fact, that prototype on the podium with you?

MR. HARDIN: PX12.

A. Yes. This is that model. And you can see in the front, we're down to the size of a normal barrel. In the back, I still haven't -- I still have a elastomer at this stage. This is still earlier stage for me. I'd had elastomer, and I've got the needle mounted in a rod, and it pulls it back up in here. When this goes down, it expands the barrel and pulls the needle rod up through there.

Q. Okay. Now, about when you were at this stage, did you start looking for outside expertise to help you with your designs in the sense of taking what you were creating and helping you create models and prototypes to

test your theories?
A. Yes. After I had the grant money, now I had the NIH on my team, so to speak. But now I had to deliver something that would be manufacturable.
And so there was a gentleman in a neighboring area of ours, and his name was Clarence Zierhut, and he had 30 years' experience in manufacturing and designing ballpoint pens which have springs, which is perfect for what I was doing. And it also was high-speed plastic automated assembly.
And I guess he also had done some work for Gillette, but he was -- he really had the background to help tell me what I needed to know for what could and couldn't be assembled at high speed/low cost.
Q. I think we have a document that reflects an early meeting with Mr. Zierhut.
So this was a document documenting the fact that you and Checkmate Engineering were going to walk forward with Mr. Zierhut and some of his folks?
A. Yes. That is correct.
Q. And it says that at the present meeting, witnessed Zierhut's prototype syringe and its operation, including retraction of the needle into the body.
Is that the prototype Mr. Zierhut built for you at your direction?

A. Yes, it is.
Q. Now, about this same period of time, did you do any comparative testing?
A. Yes, I did.
Once I had gotten this reduced model down, I did a comparative test between that product and Becton Dickinson's Safety-Lok, which is one of these two-handed sheathing devices where they hold a sheath out.
Q. Okay.
MR. HARDIN: Can we see PX26 on Page 46 of that document?
Q. (By Mr. Hardin) Now, this document is an extensive document. This is a document -- why don't you tell the jury why this document was written up, because it's a long document.
A. After you complete -- under the Small Business Innovative Research Program, they give you the first phase, but there's no guarantee of the second phase. When you completed the 50,000-segment, you write up what you've done, and then you propose for Phase 2 to continue your work. And they read your document to see what you've done, what you've accomplished. And then they look to see what you're proposing to do with the next phase.
And then for the next phase, they had a

500,000-dollar limit, and they gave me 600,000, I think, because they knew that I was working on a serious problem.

But in that grant, I have to write up both what I've done and what I plan to do with the taxpayers' money.

Q. Okay. And in this grant, you did the comparative testing. It talks about here was the comparison of your device in its rough prototype form with the then Safety-Lok syringe from Becton Dickinson.

A. That's correct.

Q. And did you share your progress on this work with anyone at that period of time?

A. Yes, I did. I sent samples to Becton Dickinson.

Q. Did you get any response?

A. Yes, I did.

Q. Now, was it -- were they interested or not interested at that time?

A. At that time, they were not interested.

Q. Okay. Now, Phase 1, we talked about Phase 1. You were given 50,000, and you were writing this long document to report on that and to try to obtain what you were eventually were awarded, which was a much larger grant.

Phase 1 ended in about December of 1992; am I correct?

A. Yes.

Q. And we saw in that Phase 1 that the panel had been concerned about the complexity of the design.

A. Correct.

Q. And did you -- even though your funding had run out in December of 1992, did you consider -- did you try any way to consider that problem, the complexity of the design?

A. Well, I took to heart what they were saying, and I had also by now spent some time with Mr. Zierhut about trying to minimize parts and simplicity and manufacturing.

And he was giving me an education on what had to be done. And I made up a kind of a game in my mind so that -- I tend to work on these things while I'm driving. I think about how they fit. And so I made up this game to see if I couldn't figure out a way where every piece in the syringe, instead of doing one thing, would maybe do like two or three things so that I'd have less pieces.

Because I had learned from Mr. Zierhut that even if a piece is a fraction of a cent, when you've got 30 billion syringes a year, it adds up into freight-car loads. And so the game was to try to figure out every possible way to save plastic and how to reduce cost and speed up assembly. So I had this game I was playing.

Q. Okay. Now, you mentioned to the jury that one of the main problems with this was the problem of the high fluid pressure -- pressures inside this syringe on the one hand and the relatively low thumb force available from small hands on the other.

Were you satisfied with the way your prototype handled that seal -- that sort of seal-and-release problem, I'll call it?

A. Well, it was kind of strange, because everybody was excited about what I had accomplished in that product, but I wasn't -- I was not satisfied with it. And the reason I wasn't satisfied is I already knew that this early -- this big design had gone down to 3cc. I knew I'd never fit it into a 1cc, which is about the size of a pencil.

And in addition to that, I just -- I felt like the extra part on the -- on the barrel, on the back that had to be expanded, it just looked like a lot of plastic. And it all had to do with how this needle rod was having to be released.

And it just seemed like to me it was just too complicated. So while everybody was complimenting me, I was going home and giving myself a hard time about it.

Q. Now, did you have sort of an aha moment that you recall when you're thinking about this problem of seal and release?

A. Yeah. As I was writing up the completion to Phase 1, I was about halfway through it, and I was driving to work. And on my way to work, I went through The Colony, and that's a little town on the way to Lewisville from Little Elm.

And I saw a donut shop on my right, and I don't know why or how that -- those things come about, but it occurred to me that you might just take like a donut and put it around a stick and then the holding force would be the donut and the stick would be the rod. And then you could pull the rod through the donut and you wouldn't have to -- you wouldn't have to have two pieces. You could do it in one.

Q. Okay. I made up for you -- because you told me the story, I made up for you a stick in a donut-shaped item.

Would you just hold it up for the jury and explain again what your thought was -- initial thought was?

A. Well, this -- this would be the needle rod, and it would have the needle -- at that time, I still had a needle rod that was pulling up from the back, and back here (indicates) was the spring, and here's the front of the syringe.

And by having this for assembly, you've got this donut. Then you're holding the rod by the donut, and the donut sets in the barrel. And then when the needle rod is slid back, then it gets to the step-down in the rod, and now there's no force that you need to pull it out, because it's not touching the rod anymore. So that's --

Q. Okay.

A. I can't explain how my mind works.

Q. Okay. Now, did you disclose that basic idea of combining those two things into one thing, essentially, in any patents?

A. Yes. I -- I filed that in my '551 patent.

Q. Okay.

A. In, I guess, September '93.

Q. Okay.

MR. HARDIN: Can we see that again? It's PX48, Figure 5.

Q. (By Mr. Hardin) While they're filing it -- finding it -- there it is.

So this is that -- we saw this earlier. So is that yellow piece there the donut, essentially?

A. Yes. And then the piece that sticks down with the spring around it is no longer a rod. I've cut the back off that rod, and now that's a needle-holder with a retaining member around it. And that donut is being held against the inside wall by friction.

Q. Okay. And do each of the patents here that we're talking about have that basic mechanism?

A. Well, all of them have the friction retaining member being held by friction or clamping on the inside wall, and all of them had a needle-holder and a spring in the front.

But there's another version that evolved later that had a bridging portion in it, and it's the bridging portion version is why we're having our difficulties with Becton Dickinson.

Q. Okay. But first, you did it this way, without that bridging portion?

A. Yes, sir.

Q. Okay. And that -- that version of it is in all your patents also, correct?

A. Yes.

Q. Okay. Now, after you did this discovery -- you did this sometime after December, and you had -- your funding had run out, correct? You weren't -- you weren't able -- your 50,000-dollar funding was gone; am

I correct?

A. Right. The way the program works, you finish Phase 1, and then until they see what you've done, they don't keep paying you. So the funding stops.

But I kept working on the project. And so during that year, until I got funding at the end of the year, I went back to funding it myself.

Q. Okay.

A. Because by that time I started thinking, hey, I may really actually pull this off.

Q. Okay. Now, in that application, though, for more government funding --

MR. HARDIN: Can we see PX26? And can we move to Page 49 of that document?

Q. (By Mr. Hardin) This is the write-up where -- where you're telling NIH that I did some stuff in the -- I got something done in your Phase 1, but then I also had another discovery after funding ran out.

MR. HARDIN: It should be Page -- PX26 at Page 49, please.

There we go.

Q. (By Mr. Hardin) Then it happened. Two months after the close of the funded Phase 1 period, in an effort to apply the 3cc technology to the smaller 1cc syringe, a major breakthrough was made.

A small plastic ring costing less than 1/20th of a cent to produce was relocated and designed in such a way to solve five separate problems.

Is that your report of your donut-shop idea in this document?

A. Yes, it is.

Q. Okay. And was anybody skeptical when you first -- let's see if we can move to the next page of this and see if there's a drawing of it.

Okay. Is this a drawing of your earliest concept of some kind of a ring on a rod?

A. When I -- when I came up with the donut on the stick, I had been making syringes where there was a rod with elastomer in the back. So my first thought was, well, I'll just go put that on my syringe that I already have.

And you can see all the way over -- like on the top view, that disk that's on the right, there's a little step-down in that stick, and that's that donut that the stick is going to be pulled up through. And that's the seal, the retainer, and the release.

And for assembly, you just slide that thing into the barrel.

Q. Okay. And later that's -- so that's one of the earliest designs. But later, that became what we've seen in the patent drawings, this concept of sliding or moving --

A. Correct.

Q. -- a rod out from capture by a ring?

A. Correct.

Q. Now, was anybody skeptical about the idea of using -- you were working with several folks. Was anybody -- was there any skepticism when you suggested that this concept would work?

A. Well, when I got to work, after driving by the donut shop, the first thing I did is ran over to tell Clarence Zierhut what I thought that I had come up with. And he -- he told me he didn't think it would work. And I felt in my mind, after spending a lot of time with this, I felt pretty sure it would.

And so I thought, well, maybe I really -- if he didn't think it would work and a lot of people in the industry might not think it would work, because he's from the industry, and so maybe I've really made an important discovery.

Q. Now, did anyone make up any test to see whether or not your basic concept would work?

A. Yeah. Clarence is not one of these guys that would just indicate something. He wanted to be sure it wouldn't work. So he made a jig where he took a rod, and he put a spring on that rod, and then he put a rubber washer. And he compressed that spring, and then he put it at different temperatures to see if -- if, in fact, it would work.

And he came back about a week and a half later and told me I was actually correct, and he had been mistaken.

Q. Okay. Now, did you make prototypes using that first basic concept?

A. Yes, I did. We made thousands of them, and, ultimately, we tested them on patients and -- and it became integrated in the technology we use today.

Q. Okay. Now, when you gave them out to nurses, is this now about 1993? Is that fair?

A. That is correct.

Q. Okay. When you were starting to give them out to nurses --

A. Well, no. I -- the grant went from '93 to '95.

Q. Okay.

A. So --

Q. In that grant period?

A. Seems to me it would have been toward the end of the grant by the time we reduced it to practice to be going over to the nurses at Texas College of Osteopathic

Medicine.

Q. Okay. So you made some of these up and took them, circa 1995, to the Texas College of Osteopathic Medicine.

And did you learn anything about how nurses were using these things by watching them?

A. Well, yeah. I was real excited, because now I had a syringe that even looked like a standard syringe, and we called it the Pop-N-Lok, because, as soon as you pushed the handle, it would retract and it would lock. And so we go over there, and I'm all excited. I've got the world's first good retractable syringe, and the nurses are using them. And then all of a sudden, bad news for me.

While they're standing there telling me how great it is and talking to me, they're kind of fidgeting with it, because they're not -- you know, now they get to handle syringes, because the needle is gone. And so they're standing there talking to me, and, you know, like on a Magic Marker, you've got a cap on the end, you know, how people click -- they pull it off and click it on. And they're not even thinking about doing it. Well, they were pulling on that, and they had accidentally pulled out the handle. And now unlike a standard syringe where the needle is fixed on the front, once that contaminated needle is in the handle of the barrel, if you pull the handle out, that needle can drop out.

And so I'm watching them talking to me, and I'm seeing them accidentally pull the handles out and going uh-oh. You know, everything worked. I got the hydraulics right. Everything's right, but now, clinically, I'm going to have an issue, because they're pulling that back out.

Q. Now, that -- that became known as the Pop-N-Lok, that design.

A. Right.

Q. And it already had some kind of a lock so that --

A. Right. As I said, you don't need a lock on a standard syringe, because the needle is out in front. So if they pull the plunger out, there's no -- they're not exposing themselves to a sharp.

But on a retractable syringe, that needle's inside and it's loose in there. And if you pull the handle out, the needle can fall. Housekeeping, somebody can get hurt with it.

Q. Okay. So what did you decide to do about that problem, that your lock wasn't even sufficient to stop this fidgeting?

A. Well, I drove back to our Lewisville office elated that they loved the technology and severely depressed, because I knew that my locking force that I had to overcome in order to lock it was already up to about 9 pounds.

And so I knew I couldn't increase my lock. And so for all their excitement, I knew that I had a real barrier, because if I made that lock tighter, then there would be no way that a nurse with a small hand would be able to fire it.

Q. All right.

A. And if I made it weaker, they would be pulling them out, and it would be clinically unacceptable.

So while they were excited, I was -- I was pretty frustrated.

Q. Okay.

MR. HARDIN: Can we see PX48, please, Figure 9?

Q. (By Mr. Hardin) Is this a -- is this a diagram of that syringe that was taken over to the nurses for them to use and look at?

A. Yes, it is.

Q. Okay. And these -- these hooks right here (indicates) in the design, is that what was supposed to lock down on this ledge right here?

A. Yes. After it pushed that retainer member forward, as it was -- as the plunger head was going over the needle-holder, there was a wall that came in from the barrel, and that hook is supposed to hook over that wall that sticks in from the barrel so that they can't pull it out.

But the problem is, if you make that tooth on the handle bigger, then it's harder to drive in there, and so you can't lock it at 9 pounds. And it was already coming loose, and it was taking 9 pounds with the other forces to put it in there.

Q. Okay. What did you do about that problem?

A. Well, it was one of those situations where I just -- you know, I was -- I didn't know what I was going to do. And I kept thinking, I can't increase the lock. I can't increase the lock. What am I going to do?

And then I had a thought that, well, if I can't increase the lock, maybe I can make it so they can't get a good grip on it. So I called Jerry, my draftsman, and I told him, hey, can you take -- we had a flat back on our original syringe. I said, can you put the collar out there so that after they have done the injection, when that handle's forward, they can't get a good grip on it, then I don't need a better lock; I can get away with my 9-pound lock, if they can't really get a good grip on it.

And so he said, sure, why not?

So then I hang up the phone and I'm thinking to myself, I'm an idiot. Why don't I extend the collar all the way back, and then I don't need any lock, and I can get rid of all 9 pounds.

And I had had three forces that I had been wrestling with for years. You had the locking force, and you had the release force at the front of the plunger, and you had the release force of the ring. And we had a machine that would show the humps from each of these forces, and I was trying to always keep them so they didn't add up to more than 9 pounds. And I realized that if I tucked the handle in the back in the second position, that whole -- a third of everything that kept me up at night for years was suddenly just gone, okay?

MR. HARDIN: Can we find that graph that he just described? While you're finding that...

Q. (By Mr. Hardin) So your idea was to bring up the collar and eliminate the lock?

A. Right.

Q. Is that the reason why today's syringe has a collar on the back?

A. Absolutely.

Q. Would you look at the last --

MR. HARDIN: There we go.

Q. (By Mr. Hardin) Is this the graph you were indicating that you had, and can you describe for the jury what we're seeing here?

A. Yes. The first force is around 5 pounds, and that's when the plunger plug starts to move. And once it starts moving and decreasing, then the other force picks up. And that's the ring coming off of the front. And then that third force -- and you can see it was killing me -- it was all the way up to just below -- somewhere up around 8 or 9 pounds. And suddenly now I don't have that third force on my new design. That part of the chart is out of my mind and out of my problem. So that was like -- that was amazing. I got -- I'll tell you, I felt adrenaline go through my body when I realized I had spent years on that. And it was over. No more lock for me.

Q. Okay. Let's look at PX52, which I think is one of the earliest, if not the earliest, drawing of this concept.

Here we go. So this is March of 1995. Your signature here.

And is this the collar, and is this the

relationship that you described that allowed you to get rid of the locking force?

A. Yes. If you look at the top drawing, you can see that the -- the plunger is all the way forward ready to draw up medicine. And the handle still sticks out the back, because the nurse has to push it all the way forward so as to create the vacuum to pull the medicine in. So it has to stick out when you start.

But in the second position, because the retainer's moving and it goes forward, that handle advances. And in the second position, that thumb cap was lodged in the back where somebody could dig it out, but they wouldn't do it unconsciously just by fiddling with it or fidgeting, like we all do when we have two things that either fit together or not.

And there was another windfall that fell out of this, which I hadn't even anticipated. But because I didn't need the lock, I didn't need the wall of the barrel to come in to catch that hook. And since I didn't need the barrel of the hook wall to come in, I didn't need a cap on the front to pull the tool out from two directions.

I could pull the rod out to form that barrel with one core pin coming out the back. And so now I could make a one-piece barrel. So it was like

everything, the lock disappeared, the handle tucked, and I had a one-piece barrel.
I mean, it was just like -- everything just seemed to start really moving in the right direction.
Q. Okay. Now, this is early 1995. Did you file a patent on that particular design?
A. Yes, I did.
Q. Okay. And was that filed in May of 1995?
A. I believe that was the '011?
Q. Yes.
A. Yes, sir.
Q. That's not a patent at issue here, but you filed that in May of 1995?
A. That is correct.
Q. And it had the one-piece body, and it had the tucking and no lock?
A. Correct.
Q. Now, did that new design affect anything that was going on with your -- with your young company in 1995?
A. Yes. Because there had been so much excitement with the Pop-N-Lok that we were trying to move forward to manufacturing, and we had already started the design of the assembly equipment that was going to try and automate -- and the goal was to make

two per second.

And I kept a metronome to listen to just how fast that was, and it sounds real fast when you're trying to get all this done. So I had to somehow integrate this change into that at our plant.

And at the same time, the company that was making the equipment was in Germany.

Q. So did you travel to Germany?

A. Yes, I did. I went over there to Germany to talk to them about how we'd have to modify the initial design. It was a better design; it was a simpler design, but, obviously, we wanted that incorporated into our assembly equipment, because it was going to help us get it cheaper and faster and better.

Q. Now, did anything in Germany happen that caused you to rethink -- you just filed a patent application in May of 1995 on essentially this design, correct?

A. Correct.

Q. This is -- this is your, what we call, friction ring design, correct?

A. Correct.

Q. Did anything happen in -- on your trip to Germany after May of 1995 that caused you to rethink the patent application you just filed?

A. Yes, it did.
Q. What happened?
A. Well, I went over there, and Hans was the person in charge of Sortimat that was making our assembly equipment. And I had asked him -- I told him I wanted two different suppliers for every type of material so that we'd never have an interruption in production. And I needed to know their needle supplier, and he sent me up to -- up north from where he was in Germany to another facility.
And I'm walking through the facility where this guy can be my second supplier for needles, if I ever have a problem in Colorado. And he's showing me all these products, which we often do as manufacturers. Everybody is proud of what they do, and they want to show people what they had.
And we're in one of these rooms where they're assembling stuff, and they had like a valve, and they had a valve with an outer circle and inner circle. And they had them on these trays on racks, and they were taking these trays and running them through an oven and when they came out, those two pieces were connected together.
And I asked him, how consistently does that work when you separate those two pieces? And he said,

well, try one. And I did. And it was -- and I said, are they all like that, and he said, yeah, they're real consistent.

And so I didn't think much more about it. We talked about needles, and I went back to my hotel room, and then that night I started having anxiety. And what had occurred to me was somebody could take that design with my tucking handle, my retainer member, my needle being put on later, my assembly and everything, and take that friction ring that I had really initially had and combine that with the needle-holder as one piece, and then take nine years of work and investment from shareholders.

Because by this time, I got shareholders, and they go in there and they make that one change, and then they're going to go, well, we're not infringing. And I'm new in the business. We're going to end up with nothing. They're going to take everything I've ever discovered just by making that one change. And so --

Q. What happened? Did you call -- did you call your lawyer?

A. I communicated -- it was 2:00 o'clock in the morning for me. He wouldn't answered if it had been 2:00 o'clock for him, I'm sure. But I called him up and told him I couldn't sleep.

And so what happened next was there was a patent filed after this that -- to protect the idea that that retaining ring in that needle-holder could be connected and bridged in a way so that we'd be protected as our factory and our people and our company went forward for everything that we had discovered in that retaining solution.

Q. So you filed your first patent in May, and then this is just -- that's May; then this is September of the same year?

A. Right.

Q. You called and started the patent process from Germany. You called the United States to get patent coverage on this concept of using a bridging portion?

A. Yes, sir.

Q. And did that become the '733 patent?

A. Yes, it did.

Q. Okay. Now, is there any limitation -- did you intend any limitation on how that bridging portion would be formed?

A. No. The idea was to protect the company from somebody taking what we had discovered with the retaining member. And so my idea was is that in any way those two could be connected would be protected, so that somebody couldn't just move in there and make that one change and say we're not infringing, and then just take a walk away with everything that -- it wasn't me.

We had the NIH, Clarence. I had a whole team of people. We had been working on this for years. And so it was -- it was to protect.

And then also to give me the option so that if some day I came back with what I'd seen in Germany, and I may still, because I will never forget how consistent those two things broke apart. We've been real busy trying to make products and develop products, but I'm not sure to this day that I don't want to go back and redo. And I get a choice to manufacture that version or the version I'm making now.

We're invested in the one we're making now. But certainly, that's something that I have a right to do, because this -- this was my invention. And I have that option.

Q. Did you -- did the way you described that separation in your patent, does it limit in any way whether that's a rupture, a fracture, a cutting, or anything else?

A. No. I didn't want to address how it was separated, because I'm protecting that part so that it doesn't matter how they break it.

If I said -- if I said, well, it had a cutter, then they'd say, well, we have a crunch bar. Well, if I have a crunch bar, they would have a pry bar.

What I'm trying to protect is that unitary piece that's frictionally held that's going to release that needle-holder and release that friction force that's holding that needle-holder in place. And so that's what I'm trying to protect, is my contribution.

Q. And is that what you feel like Becton Dickinson has taken?

A. Well --

MR. BECK: Your Honor, may we approach the bench?

THE COURT: Very well.

This is probably a good time for the jury to go to lunch, and we'll try to start back at 1:30.

COURT SECURITY OFFICER: All rise.

(Jury out.)

THE COURT: Mr. Shaw, you may have a seat.

Yes, Mr. Beck?

I don't really think this is necessary to do this at the bench, but I guess we can.

(Bench conference.)

MR. BECK: Your Honor, I'm going to object to -- he has specifically testified under oath that he's not giving any opinions on validity. There's nothing in his expert report --

THE COURT: I'm assuming he hasn't been designated as an expert.

MR. HARDIN: Actually, he has. But -- but -- but -- but I withdraw that question, the one question.

THE COURT: I knew that's where we were probably going.

MR. HARDIN: I withdraw that one question.

THE COURT: Not designating him as an infringement expert, other than generally maybe saying he thinks they're infringing.

MR. HARDIN: That's all we --

THE COURT: But as far as trying to --

MR. HARDIN: No, we're not going there, Your Honor.

THE COURT: As far as him giving an infringement opinion, I'm not going to allow that.

MR. HARDIN: That's not going to happen.

(Bench conference concluded.)

THE COURT: All right. We'll be in recess.

COURT SECURITY OFFICER: All rise.

(Recess.)

* * * * *

CERTIFICATION

I HEREBY CERTIFY that the foregoing is a true and correct transcript from the stenographic notes of the proceedings in the above-entitled matter to the best of my ability.

/s/________________________ ____________________
SUSAN SIMMONS, CSR Date
Official Court Reporter
State of Texas No.: 267
Expiration Date: 12/31/10

/s/____________________ ________________
JUDITH WERLINGER, CSR Date
Deputy Official Court Reporter
State of Texas No.: 731
Expiration Date: 12/31/10